US005919125A

United States Patent [19]

Berch

[11] Patent Number: 5,919,125

[45] Date of Patent: Jul. 6, 1999

[54] **CENTRIFUGE BOWL FOR AUTOLOGOUS BLOOD SALVAGE**

[75] Inventor: **Stephen William Berch**, Arvada, Colo.

[73] Assignee: **COBE Laboratories, Inc.**, Lakewood, Colo.

[21] Appl. No.: **08/891,471**

[22] Filed: **Jul. 11, 1997**

[51] **Int. Cl.**[6] **B04B 1/06**; B04B 7/08

[52] **U.S. Cl.** **494/67**; 494/41; 494/43; 494/65

[58] **Field of Search** 494/41, 43, 65, 494/67

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,409,213	11/1968	Latham, Jr. .	
3,411,450	11/1968	Clifton .	
3,470,824	10/1969	O'Connor .	
3,487,784	1/1970	Rafferty et al. .	
3,647,324	3/1972	Rafferty et al. .	
3,785,549	1/1974	Latham, Jr. .	
3,957,389	5/1976	Rafferty et al. .	
3,970,408	7/1976	Rafferty et al. .	
4,037,984	7/1977	Rafferty et al. .	
4,059,108	11/1977	Latham, Jr. .	
4,086,924	5/1978	Latham, Jr. .	
4,135,253	1/1979	Reich et al. .	
4,185,617	1/1980	Hutchins .	
4,257,744	3/1981	Watson .	
4,300,717	11/1981	Latham, Jr. .	
4,304,532	12/1981	McCoy .	
4,352,646	10/1982	Laing et al. .	
4,380,416	4/1983	Menager .	
4,408,952	10/1983	Schweingurter .	
4,589,822	5/1986	Clausen et al. .	
4,606,698	8/1986	Clausen et al. .	
4,643,641	2/1987	Clausen et al. .	
4,668,214	5/1987	Reeder	494/37
4,678,409	7/1987	Kurokawa .	
4,684,361	8/1987	Feldman et al.	494/41
4,688,998	8/1987	Olsen et al. .	
4,722,661	2/1988	Mizuno .	
4,898,518	2/1990	Hubbard et al. .	
4,943,273	7/1990	Pages	494/41
4,983,158	1/1991	Headley	494/41
4,984,972	1/1991	Clausen et al. .	
5,021,048	6/1991	Buckholtz .	
5,141,486	8/1992	Antwiler	494/37
5,147,186	9/1992	Buckholtz .	
5,312,319	5/1994	Salter	494/41
5,405,308	4/1995	Headley et al.	494/67
5,514,070	5/1996	Pages	494/41

FOREIGN PATENT DOCUMENTS

0 619 145 A2	10/1994	European Pat. Off. .
0 664 159 A1	7/1995	European Pat. Off. .
0 682 953	11/1995	European Pat. Off. .
WO 93/20860	10/1993	WIPO .

OTHER PUBLICATIONS

COBE Laboratories, Inc., "COBE BRAT 2 Operators's Manual" (undated).

Haemonetics Corporation, "Cell Saver HaemoLite 2 Autologous Blood Recovery System Owner's Operating and Maintenance Manual," Apr. 1989.

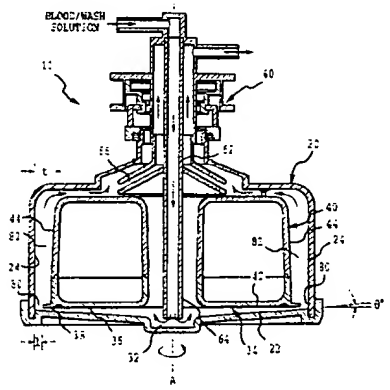
Primary Examiner—John Kim

Attorney, Agent, or Firm—Holme Roberts & Owen LLP

[57] **ABSTRACT**

An improved centrifuge bowl and related system is disclosed which is particularly apt for enhanced autologous blood salvage applications. The centrifuge bowl assembly includes a rotatable outer bowl, an internal spacer interconnected therewithin, and a stator assembly for introducing/removing fluid during rotation of the outer bowl and internal spacer. The outer bowl and internal spacer are configured to define a lateral passageway at the bottom of the assembly which terminates in an upward-facing port for fluid passage therethrough into an annular, cylindrical collection region. The annular port may be defined by a peripheral fin on the spacer and may be of a width that is less than the width of the cylindrical, annular collection region, wherein separated blood components (e.g. red blood cells) will accumulate across the width of the port during blood fill/wash cycles. As a result, enhanced washing is realized while maintaining throughput rates.

18 Claims, 4 Drawing Sheets



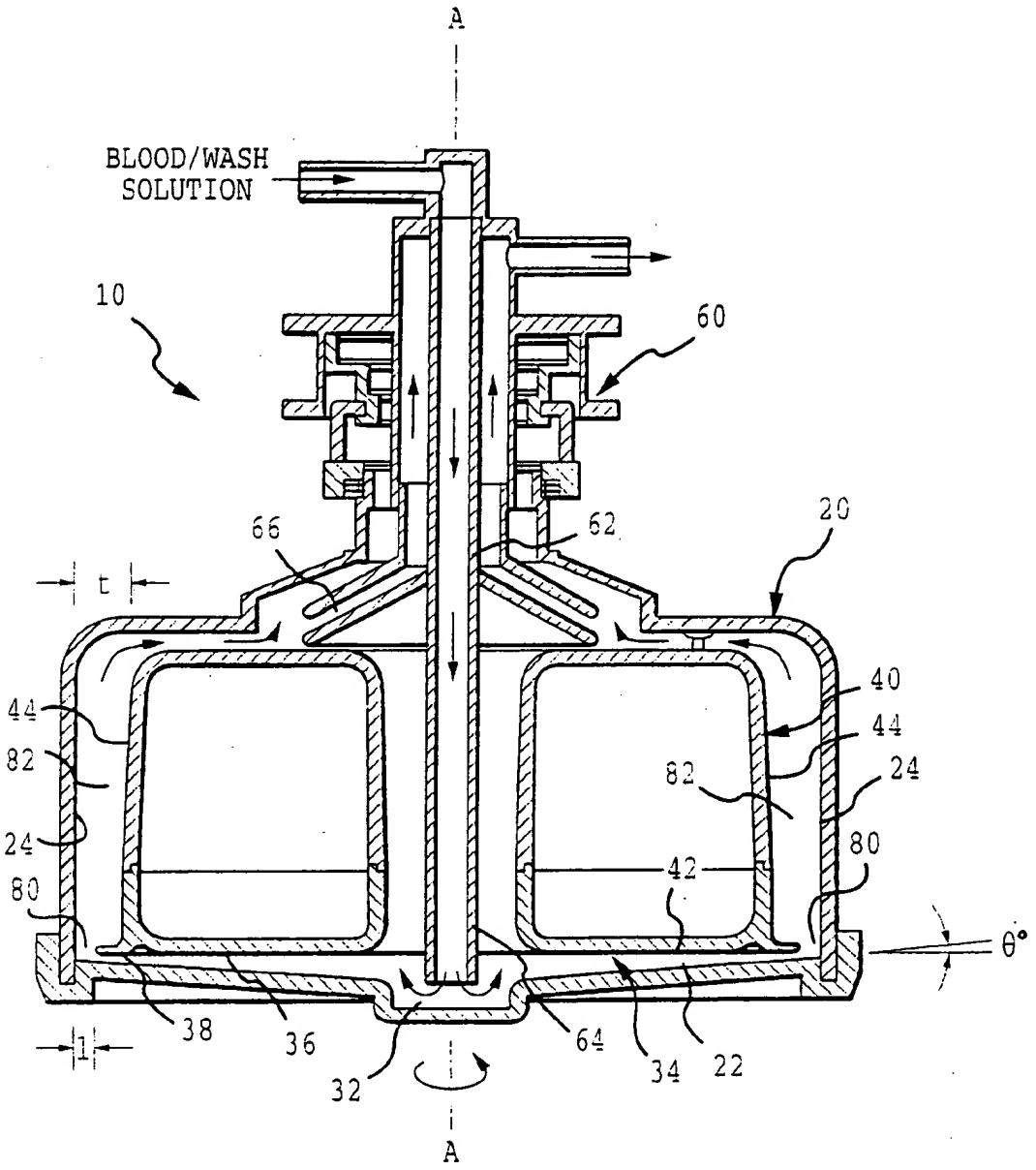

A
BLOOD/WASH SOLUTION
10
60
66
62
20
t
40
44
82
24
80
42
θ°
38
36
64
34
22
32
l
A

FIG.1

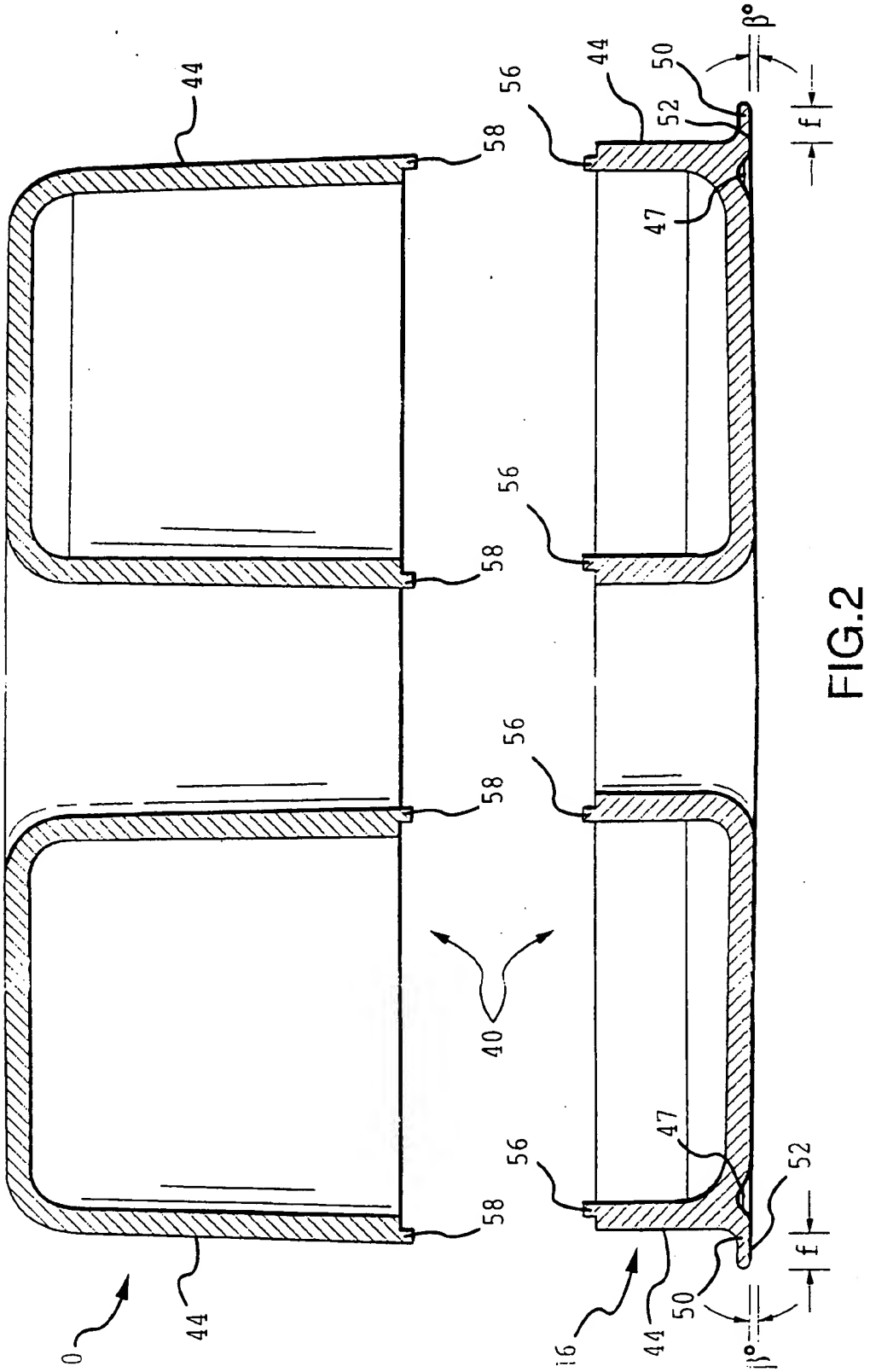


FIG.2

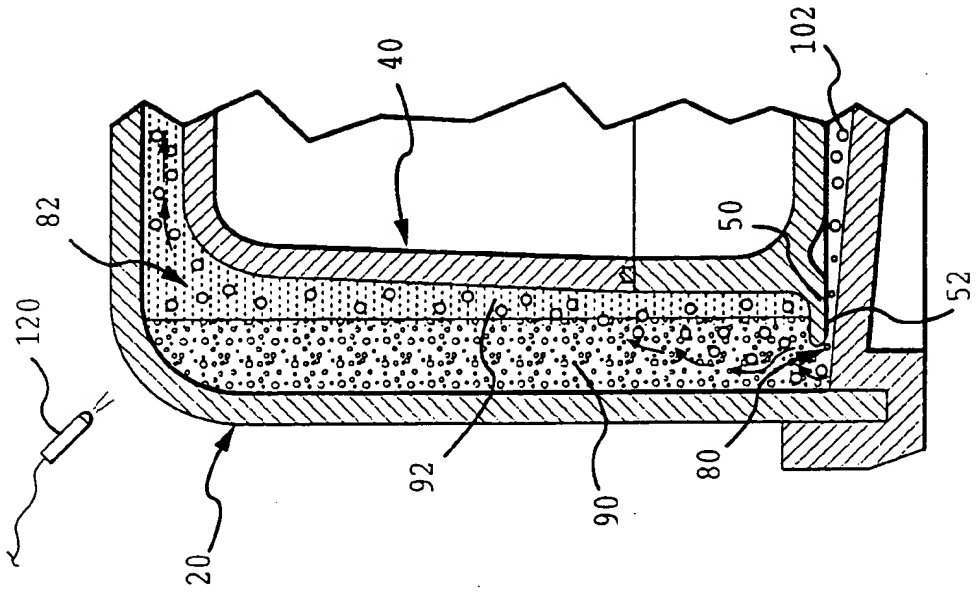


FIG.3B

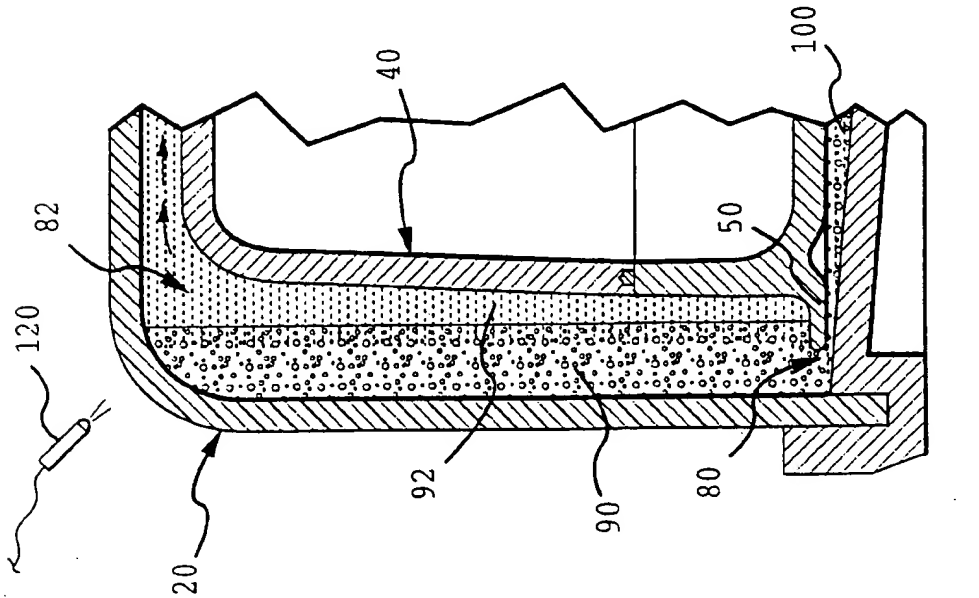


FIG.3A

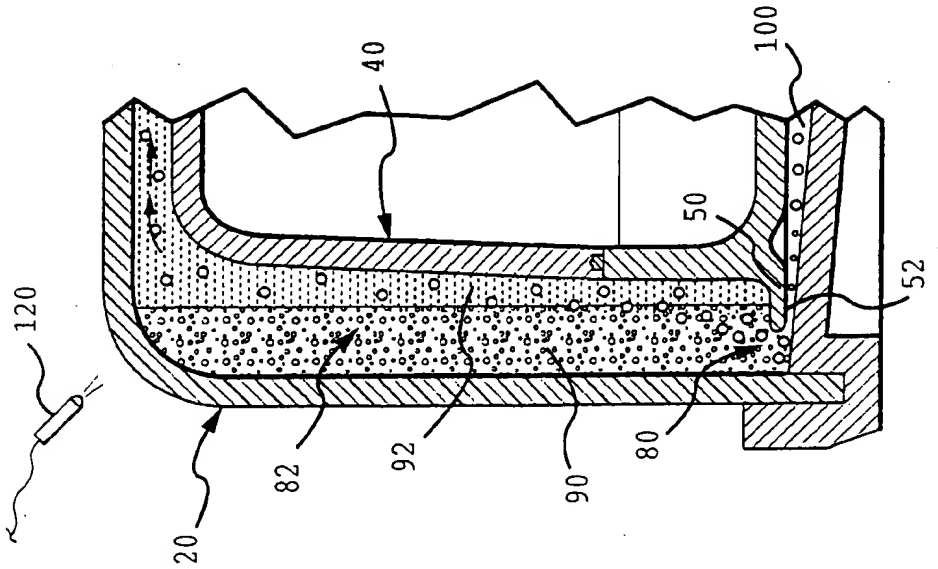


FIG.3D

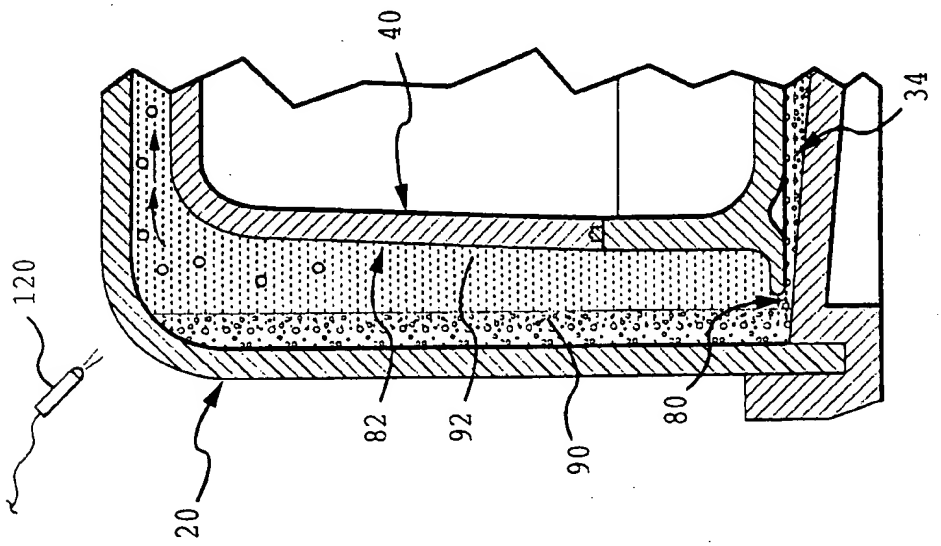


FIG.3C

CENTRIFUGE BOWL FOR AUTOLOGOUS BLOOD SALVAGE

FIELD OF THE INVENTION

This invention pertains to centrifuge bowls utilized in extracorporeal blood transfer applications, and more particularly, to a centrifuge bowl that provides for fluid flow therethrough during rotation and that is particularly apt for enhanced autologous blood salvage operations.

BACKGROUND OF THE INVENTION

The popularity of autologous blood salvage continues to increase as its many advantages are recognized. Relative to the use of donor blood transfusions, the collection of a patient's blood during an intraoperative procedure and subsequent re-infusion of separated red blood cells (RBCs) into the patient reduces concerns relating to the possibility of disease transmission. The procedure also reduces concerns regarding fibrile/allergic reactions. Further, autologous blood recovery procedures provide ready RBC availability, reduced compatibility test needs, and improved RBC quality advantages.

In known autologous blood salvage techniques, blood is removed from or about a surgical site via a hand-held suction device, mixed with an anticoagulant, and transferred to a reservoir for subsequent transfer and batch processing. In connection with such collection/transfer, the blood is typically filtered to remove debris and defoamed to remove gaseous components. During processing, the blood and a wash solution are separately pumped in sequence through a rotating centrifuge to separate and wash accumulated red blood cells. Following one or more blood fill/RBC separation and wash cycles, the accumulated red blood cells are removed from the centrifuge bowl for subsequent re-infusion to the patient.

During the iterative fill/wash cycles it is important to closely control/monitor the speed and level of RBC collection in order to obtain a high quality RBC product as rapidly/efficiently as possible (e.g. to obtain a high hematocrit and high quality wash, with minimal RBC spillover in the wash solution). In this regard, the reduction of blood processing time is advantageous since, inter alia, it desirably reduces medical personnel time demands and otherwise advantageously allows for expeditious reinfusion of the RBC product to the patient.

With the increase in popularity of blood salvage techniques, heightened performance objectives are being considered. In particular, the enhanced washing of RBCs during rapid processing is of specific interest. As will be appreciated, washing of the red blood cells serves to dilute and remove soluble molecules suspended in the plasma, such as plasma-free hemoglobin and anticoagulants heparin). Additionally, activated/nonactivated clotting factors are removed. Further, it is desirable that washing remove activated platelets/white blood cells. Correspondingly, it is desirable to avoid the accumulation of deposits of white blood cells and platelets in the centrifuge bowl during processing so as to reduce any risk of removal of such deposits with the harvested RBCs. (See e.g., Bull et al., "Enhancing the Safety of Intraoperative RBC Salvage", The Journal of Trauma (March 1989)).

SUMMARY OF THE INVENTION

In view of the foregoing, a primary objective of the present invention is to provide an improved centrifuge bowl and corresponding blood processing system which achieves enhanced washing of separated blood components, and which is particularly apt for autologous blood salvage operations. In the later regard, it is an objective of the present invention to provide for the collection of a red blood cell product having a relatively high hematocrit (e.g. at least above 42% and more preferably at least about 50%), with high "washout efficiency" (e.g., providing for heparin mass reduction of at least about 98%), and wherein processing rates can be maintained at a relatively high level (e.g., blood fill rates of at least about 300 ml./min. and wash solution inlet rates of at least about 500 ml./min.).

These objectives and additional advantages are realized in the present invention which provides for the axial flow of blood into the bottom of a rotating centrifuge bowl, and resultant spinning of such blood outwardly from the bowl's center axis through a substantially lateral and radiating passageway. The blood then passes through an upwardly oriented port, or outlet, from the lateral passageway, and engages a substantially vertical sidewall of an outer bowl and accumulates in an annular fluid bed. Such fluid bed is contained in a cylindrical, annular collection ring between the sidewall of the outer bowl and a substantially vertical sidewall of an internal spacer.

By virtue of the described arrangement, at least one predetermined, heavier component of the blood to be separated and harvested for reinfusion (e.g. red blood cells)will accumulate in an outer layer of the annular fluid bed during the blood fill cycle, while other undesired components will accumulate in an inner layer of the annular fluid bed. When the inner layer of undesired compounds reaches a predetermined level (i.e. relative to the rotational axis), the undesired components will flow out of the top of the rotating bowl. The outer layer of separated components will be "packed" in a substantially uniform manner along the height of the outer layer. More particularly, while the density of collected components (e.g., RBCs) decreases according to distance from the rotational axis (i.e., less dense as distance decreases), such density gradient will be substantially uniform throughout the height of the outer layer.

Upon terminating the flow of blood into the centrifuge bowl, a predetermined volume of wash solution is flowed into the rotating bowl through the same pathway as the blood, and directed into the accumulated outer layer of separated components to achieve a degree of washing thereof. Such wash solution and additional undesired blood components washed from the outer layer will accumulate in the inner layer of the annular fluid bed during the wash cycle and will flow out of the top of the rotating bowl.

Of importance, the outer layer of separated blood component(s) will become increasing thicker (i.e. the vertical surface of the outer layer will progress towards the axis of rotation) during the blood fill cycle, while maintaining a substantially constant density gradient throughout the height of the cylindrical, annular collection region. In this regard, the thickness of the outer layer may advantageously exceed the width of the port of the lateral passageway, wherein the outer layer advantageously extends across the lateral extent of the port prior to a wash cycle. In this regard, the present invention provides for enhanced washing of the outer layer components by introducing the wash solution directly into the bottom of the accumulated outer layer of separated component(s). That is, washing of the separated component(s) is enhanced as the wash solution passes upwardly, directly therethrough and laterally therethrough (i.e., towards the rotational axis) to the inner layer where it accumulates for removal. In conjunction with such washing

during blood salvage applications, the flow of the wash solution may particularly enhance removal of plasma-free hemoglobin (e.g. in cases exhibiting significant hemolysis) that may accumulate during the blood fill cycle within the outer layer together with desired red blood cells.

In this regard, it should be noted that termination of the blood fill cycle may be triggered either automatically or manually. Manual triggering may be based upon user detection of a predetermined color in a transparent outlet flow line from the centrifuge bowl. Automatic termination may be provided by positioning an optical assembly, having an infrared light source (e.g. for emitting light of a wavelength that is readily absorbed by red blood cells) and a corresponding light detector, immediately adjacent to the top of the outer centrifuge bowl (e.g. constructed of clear plastic). When the outer layer accumulates to a predetermined volume the amount of light detected will fall below a predetermined level so as to automatically terminate the fill cycle and start the wash cycle. As will be appreciated, in blood salvage applications the presence of significant levels of plasma-free hemoglobin within the outer layer comprising accumulated red blood cells can be "detected" so as to result in early termination of the fill cycle. When this occurs with the present invention, the subsequent flow of wash solution directly into the bottom of the accumulated outer layer serves to enhance separation of the plasma-free hemoglobin from the RBCs, and to effectively push the plasma-free hemoglobin out of the bowl during the wash cycle so as to enhance the hematocrit of the harvested outer layer product. When this occurs the source/detector can also be provided to detect if/when the outer layer recedes below the predetermined desired volume so as to trigger subsequent fill and wash cycles, wherein the desired volume and quality of product can be obtained.

When the desired volume of the outer layer comprising the desired, separated component (e.g. RBCs) has been accumulated and washed, the outer layer may be removed from the centrifuge bowl. For example, the centrifuge bowl may be emptied by terminating rotation of the centrifuge bowl and pressurizing the bowl so as to flow the accumulated outer layer back through the bottom passageway and axially out of the bowl for collection in a reservoir and subsequent patient reinfusion.

In accordance with the present invention, a rotatable centrifuge bowl assembly may be employed which includes a cylindrical outer bowl, a cylindrical internal spacer interconnected within the outer bowl for rotation therewith, and a stationary stator assembly for introducing fluid to and removing fluid from an annular, cylindrical collection region defined between the vertically straight, internal sidewall of the vertically straight, outer bowl and the outer sidewall of the internal spacer. During use, such annular, cylindrical collector region contains an annular fluid bed comprising inner and outer layers as noted above. The internal spacer and outer bowl are configured and interconnected so as to further define a substantially lateral, radiating passageway at the bottom of the centrifuge bowl assembly, and an annular upward facing port from such lateral passageway vertically into the cylindrical, annular collection region. Importantly, the width of the annular port is less than the width of the annular, cylindrical collection region.

Preferably, the bottom external surface of the internal spacer is substantially flat while the opposing internal surface at the bottom of the outer bowl angles slightly upward and outward to define a narrowing, central portion of the lateral passageway. Further, at the peripheral extreme of such passageway, it may be preferable to provide a passageway portion having a cross-sectional size that is maintained or even increases, wherein fluid passing through the peripheral portion is directed into the annular, collection region at an acute angle transverse to the outer layer of the annular fluid bed described above.

More particularly, an internal spacer can be employed which includes an annular, continuous fin projecting outwardly from the outer sidewall of the spacer, most preferably at and completely about the bottom peripheral extreme thereof. Such fin may advantageously extend outward a predetermined distance from the circular sidewall of the internal spacer, wherein enhanced washing benefits can be realized during use (e.g. by providing for directed passage of wash solution towards and/or directly into accumulated red blood cells during filling/washing steps). Relatedly, it has also been recognized that it may be desirable to angle a circular fin slightly upward, and most preferably by an angle at least commensurate with, and preferably greater than the upward and outward angulation of the base floor of the outer bowl. More particularly, it has been determined that a fin having an upward angulation of at least about 3° to 27° relative to horizontal is desirable, and even more desirably between about 3° and 7°.

Further, it has been determined that a fin having a predetermined length (i.e. outward extension relative to the outer sidewall surface of the internal spacer) which exceeds about 20% of the width of the annular, cylindrical collection region is preferable, and even more preferably which is between about 25% and 60%. By way of particular example, where the width of the annular, cylindrical collection region is about 0.28", it is preferable to utilize a fin length of at least about 0.06" to about 0.17".

In one embodiment, the outer bowl and internal spacer can each be of a two-piece plastic construction. Specifically, the internal spacer may comprise upper and lower members which are adjoined (e.g. with ultrasound welding) after separate molding (e.g., via injection-molding techniques). In the later regard, it has been determined that the length and angulation of the above-noted lateral passageway and outwardly extending fin can be of significant importance, and therefore reliable molding of the lower member of the internal spacer is of particular interest. Correspondingly, it has been found that, by defining (e.g., during molding) an annular recess in the bottom surface of the bottom member of the internal spacer, immediately adjacent to the outwardly extending fin, the desired configuration and orientation of the fin can be reliably maintained.

Advantages and variations of the present invention will become apparent to those skilled in the art upon further consideration.

DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a cross-sectional view of one centrifuge bowl assembly embodiment of the present invention.

FIG. **2** is a cross-sectional assembly view of the internal spacer utilized in the embodiment of FIG. **1**.

FIGS. **3**A and **3**B, and FIGS. **3**C and **3**D illustrate various stages of fill and wash cycles within the centrifuge bowl assembly embodiment of FIG. **1**.

DETAILED DESCRIPTION

The centrifuge bowl assembly **10** illustrated in FIGS. **1**-**3** comprises an outer bowl **20**, internal spacer **40** interconnected within outer bowl **20** for driven rotation therewith about axis AA, and a stationary stator assembly **60** for

introducing/removing fluids to/from the assembly **10**. The illustrated embodiment will be described in relation to an autologous blood salvage application, but it will be understood that the invention may have broader application.

As shown in FIG. **1**, stator assembly **60** includes a fluid inlet tube **62** having a bottom end **64** positioned in bottom well region **32** for the sequential introduction of salvaged blood and wash solution and for removal of the harvested RBC product during use. The bottom well region **32** is fluidly interconnected to an outwardly, radiating passageway **34** defined between the internal, bottom surface **22** of the outer bowl **20** and the external, bottom surface **42** of internal spacer **40**. The passageway **34** includes a narrowing, central portion **36** and peripheral portion **38**. As illustrated, the central portion **36** narrows by virtue of the upward and outward sloping of the bottom surface **22** of outer bowl **20** at an angle of θ° (e.g., about 3°) relative to the horizontal bottom surface **42** of internal spacer **40**. The passageway **34** terminates in an upwardly-oriented port **80** to permit salvaged blood and wash solution passage therethrough into a cylindrical, annular collection region **82** defined between the straight, inner surface of the straight, substantially vertical sidewall **24** of the outer bowl **20**, and the straight, substantially vertical outer surface of sidewall **44** of the internal spacer **40**. The width l of port **80** is less than the width t of the annular, collection region **82**. The annular, collection region **82** is in fluid communication with fluid removal channels **66**, included within the stator assembly **60**, as will be further described. The stator assembly **60** provides for a rotating seal between stator assembly **60** and the outer bowl **20**, e.g., as taught by U.S. Pat. No. 4,684,361.

As shown in FIG. **1**, the port **80** is defined between the substantially vertical, inner surface of side wall **24** and the outer bowl **20** and the peripheral edge of an annular fin **50** protruding at and about the bottom peripheral extreme of internal spacer **40**. In this regard, and as best illustrated in FIG. **2**, annular fin **50** may be configured so that a bottom surface **52** of annular fin **50** angles upwardly and outwardly at an angle of β° (e.g. about 3° to about 27°, and preferably about 3° to 7°) relative to the horizontal, bottom surface **42** of internal spacer **40**.

To facilitate manufacture, internal spacer **40** may comprise injection-molded bottom section **46** having annular fin **50** integrally defined therewith, and injection-molded top section **48**. The bottom section **46** and top section **48** may be assembled together via interfacing projections on bottom section **46** and **58** on top section **48**, respectively, wherein the bottom and top sections **46** and **48** are secured by melting the interfacing projections **56** and **58** together via ultrasonic welding during assembly. Of note, in order to maintain the desired angulation of fin **50** (i.e. at the desired angle β°), an annular recess **47** may be defined in bottom member **46** upon molding. More particularly, the inclusion of recess **47** significantly reduces any distortion of fin **50** that may otherwise occur upon cooling after molding, wherein the angulation and overall profile of fin **52** is maintained substantially uniform about the circular periphery thereof.

Preferably, fin **50** is of a length f, wherein the ratio of fin **50** length f to annular collection region **82** width t is at least about 0.2, and even more preferably between about 0.25 to 0.60. In this regard, it has been determined that, where the diameter of internal sidewall **27** of bowl **20** is 5.135", the diameter of external sidewall **44** of spacer **40** is 4.57", and the height of collection region **82** is about 2.3", fin **50** should have a length of between about 0.06" to 0.17". Specifically, in such an arrangement a fin **50** length of about 0.09", fin **50** thickness of about 0.06", and fin **50** surface **52** upward angulation β° of about 4° provides for excellent results.

Referring now to FIGS. **3A** and **3B**, progressive blood fill and wash steps of an autologous blood salvage operation will be described. Generally, FIGS. **3A** and **3B** illustrate the successive passage of salvaged blood then wash solution into an annular collection region **82** of a rotating centrifuge bowl assembly **10**, wherein red blood cells accumulate in an outer layer **90** in the annular collection region **82**, and undesired blood components and wash solution accumulate and are removed from an inner layer **92** in the annular collection region **82**.

More particularly, FIG. **3A** illustrates introduction of salvaged blood **100** during a filling step. As shown, salvaged blood **100** passes through passageway **34** and into the annular collection region **82** via port **80**. By virtue of the rotation of the outer bowl **20** and internal spacer **40**, red blood cells are accumulated in an outer layer **90**, undesired blood components accumulate in an inner layer **92**. Such undesired components may include, for example, an anticoagulent (e.g. heparin), white blood cells and platelets, plasma-free hemoglobin and activated/inactivated clotting factors.

As shown, red blood cells will continue to accumulate in the outer layer **90** while the undesired components accumulate in the inner layer **92** and are removed through passageway **66** (not shown in FIG. **3A**). Of importance, it can be seen that the outer layer **90** accumulates to a thickness sufficient to completely cover port **80**.

Of related importance, due to the configuration at bowl **20** and spacer **40**, the density gradient across and thickness of the outer layer **90** is substantially constant along the vertical extent thereof. As a result, relatively high blood fill rates (e.g. at least about 300 ml./min., and most typically about 400 ml./min., for 250 ml. bowl containment volume) and relatively high wash solution input rates (e.g. at least about 500 ml./min., and most typically about 800 ml./min., for 250 ml. bowl containment volume) can be realized.

In the latter regard, FIG. **3A** illustrates the inclusion of an optical sensor assembly **120** positioned adjacent to the top of outer bowl **20** for detecting when the outer layer **90** reaches a predetermined volume so as to automatically terminate the salvaged blood filling step and initiate the wash step. Such predetermined volume may be advantageously selected to provide for outer layer **90** coverage of port **80**. By way of example, optical sensor assembly **120** may include an infrared light source and detector for emitting and detecting light having a predetermined center-wavelength that will generally be more readily absorbed by red blood cells than undesired components accumulating in layer **92**. Therefore, since optical sensor assembly **120** is angled (e.g. at about 45°), emitted light will pass through the clear bowl **20** and reflect off of the upper radius of spacer **40** (i.e. adjoining the sidewall **44** and top of spacer **40**) and back to optical assembly **120** at a predetermined minimum intensity level until/unless the outer layer **90** has accumulated to the above-noted, predetermined volume. At that point, the red blood cells in outer layer **90** will effectively block the light from returning to optical assembly **120** and thereby trigger the noted response.

FIG. **3B** illustrates a wash cycle during which a predetermined volume of wash solution **102** (e.g., 1000 ml. of saline solution for a 250 ml. bowl containment volume) is introduced through the passageway **34** and port **80** into the annular collection region **82**. More particularly wash solution **102** is introduced directly into the bottom of outer layer **90**. Further, due to the rotation of outer bowl **20** and inner bowl spacer **40**, as well as the upward and outward angu-

lation of the bottom surface **52** of fin **50** (e.g. at about 4° relative to horizontal), at least a portion of wash solution **102** is directed through vertical port **80** at an acute, upward angle relative to horizontal. As will be appreciated, such flow of wash solution **102**, when coupled with the uniform packing of red blood cells within outer layer **90**, allows an enhanced degree of washing to be realized by the present invention. That is, wash solution **102** will penetrate and mix into outer layer **90** so as to contact and wash undesired components from the red blood cells. In this regard, it will be appreciated that enhanced washing is achieved in the present invention by virtue of the position and configuration of port **80** and fin **50** as well as the vertical configuration of the sidewalls **24** and **44** of bowl **20** and spacer **44**, respectively.

FIG. 3C illustrates a second filling step, wherein additional salvaged blood **100** is introduced through passageway **34** into collection region **82**. As shown, the red blood cells continue to accumulate in the outer layer **90** while the undesired components accumulate in the inner layer **92** for removal through passageway **66** (not shown). Of importance, it can be seen that at the end of the second filling step (i.e. FIG. 3D) the outer layer **90** is again thick enough to completely cover port **80**.

FIG. 3D shows a second washing step, wherein wash solution **102** is introduced directly into the bottom of outer layer **90**. As will be appreciated, such flow of wash solution **102**, when coupled with the uniform packing of red blood cells within outer layer **90**, allows an enhanced degree of washing to be realized. In this regard, the wash solution **102** is able to move through and contact a significant portion of the RBC's within outer layer **90**.

It should be noted that when there is significant hemolysis in the salvaged blood, a relatively large amount of plasma-free hemoglobin may accumulate during filling with the red blood cells in the outer layer **90** and thereby trigger detection by optical sensor assembly **120**. Should this occur in use of the present invention, the wash cycle illustrated in FIG. **3B** provides for enhanced washing of plasma-free hemoglobin from the red blood cells and will effectively "push" out the plasma-free hemoglobin via passageway **66**. As such, and as shown in FIG. 3C, upon completion of the wash step, the accumulated outer layer **90** comprising the red blood cells may recede to a volume less than the predetermined desired volume that triggered termination of the initial filling step and initiation of the initial wash step.

In such instances, the sensor assembly **120** may be provided so as to detect such condition, wherein a second filling step can be automatically initiated and carried out as shown in FIG. **3D**. Such second filling step may be terminated in the same manner as described above in relation to FIGS. **3A** and **3B**. Iterative fill and wash steps may continue until the desired predetermined volume of the outer layer **90** comprising red blood cells is achieved.

When a predetermined, desired volume of outer layer **90** is obtained, the outer layer may be emptied from bowl **20** via tube **62**. For example, rotation of bowl **20** may be terminated and bowl **20** may be pressurized so as to cause the accumulated RBC-containing product to flow through port **80**, passageway **34** and out of the bowl via tube **62**. The harvested product may then be collected in a reservoir for subsequent patient reinfusion.

By virtue of the enhanced washing provided by the present invention, an improved RBC blood product can be attained. Specifically, mass anticoagulant removal of at least about 98% can be realized. That is, for example, where the blood introduced for processing comprises a given number of units of anticoagulent (e.g. heparin), at least about 98% of the mass of such anticoagulent may be removed via washing, wherein the final, outer layer of RBC-containing product includes less than about 2% of the mass of the anticoagulant. Further, the enhanced washing can be obtained while maintaining blood fill rates into bowl **20** of at least about 300 ml./min. and more typically about 400 ml./min., and wash solution inlet rates of at least about 500 ml./min. at more typically about 800 ml./min. Additionally, the resultant RBC product can be provided with a hematocrit of above about 42%, and more typically of at least about 50%.

EXAMPLE

Comparative testing of the present invention and a prior art device, as taught by U.S. Pat. No. 4,684,361, has confirmed that the present invention yields enhanced red blood cell washing, while maintaining a relatively high hematocrit. In particular, such testing reflects a capability to decrease heparin loading in the resultant red blood cell product by more than 50% relative to such prior art device.

In the test, both the prior art device and an embodiment of the present invention, as described above, were sized to define an annular collection region having a volume of 250 ml. The devices utilized in the testing were commonly configured except for the inclusion of a fin **50** on internal spacer **40** in the inventive embodiment, such fin having a length of about 0.12" and defining a port **80** width of about 0.174". Multiple fill/wash cycles were conducted with a common protocol utilizing plasma dilute blood. The results of the study are set forth in Table 1. As will be appreciated, these results indicate that total heparin mass reduction is enhanced with the present invention relative to the prior art device.

TABLE 1

	Cycle	Plasma Dilute Blood In (ml)	Wash Vol. (ml.)	Inlet Heparin Mass (units/ml.)	Outlet Heparin Mass (units/ml.)	Heparin Mass Reduction (units/ml.)
Prior Art Device	1	835	1000	3193.88	167.27	94.76%
	2	828	1000	3167.10	195.00	93.84%
	3	832	1000	3182.40	212.54	93.32%
Present Invention	1	764	1000	3441.82	73.29	97.87%
	2	835	1000	3761.68	78.41	97.92%
	3	831	1000	3743.66	75.90	97.97%

What is claimed is:

1. A centrifuge bowl assembly for extracorporeal blood processing, including:

a rotatable cylindrical outer bowl having a bottom internal surface and an adjoining substantially vertical, internal sidewall;

a cylindrical internal spacer, interconnected within said outer bowl for driven rotation therewith, said internal spacer having a bottom external surface an adjoining substantially vertical, external sidewall, and an annular fin having a peripheral edge, said fin extending outwardly from said external sidewall of said spacer, wherein the bottom internal surface of said outer bowl and the bottom external surface of said internal spacer define an outwardly extending passageway therebetween terminating in an annular, upward-facing port between said peripheral edge of said fin and said outer bowl internal sidewall, said port having a first width, and wherein said substantially vertical, internal sidewall of said outer bowl and the substantially vertical, external sidewall of said internal spacer define a substantially cylindrical, annular collection region therebetween, said substantially cylindrical, annular collection region being in fluid communication with said annular, upward-facing port and having a second width greater than said first width of said port;

a stator assembly, interconnected to a top end of said outer bowl, for introducing blood and a wash solution into said passageway and to remove the wash solution and undesired blood components in the introduced blood from said cylindrical, annular collection region during rotation of said outer bowl and internal spacer, wherein red blood cells in the introduced blood accumulate in order substantially cylindrical annular ring immediately adjacent to said substantially vertical, internal sidewall of said outer bowl, said outer ring of accumulated red blood cells having a substantially uniform thickness and being packed substantially uniformly along the height thereof, and said outer ring of accumulated red blood cells having a substantially uniform density gradient along the height of the outer ring, wherein said outer ring of red blood cells accumulates to a thickness sufficient to cover said port prior to introduction of wash solution, and wherein during introduction of wash solution at least a portion of said wash solution flows through said port and said wash solution is directed by said fin into the bottom of said outer ring to wash said accumulated red blood cells, said wash solution and additional blood components accumulating in an inner layer of the annular collection region.

2. A centrifuge bowl as recited in claim 1, wherein said passageway includes a central portion and an adjoining peripheral portion, said peripheral portion being disposed between the bottom internal surface of the outer bowl and said annular fin extending outwardly from said external sidewall of said internal spacer.

3. A centrifuge bowl as recited in claim 2, wherein said peripheral portion is flared relative to said central portion.

4. A centrifuge bowl as recited in claim 2, said fin having a bottom surface which angles upwardly and outwardly at an angle of between about 3° and 27° relative to horizontal, wherein said wash solution is directed into said annular collection region at an acute angle transverse to said outer ring of accumulated red blood cells.

5. A centrifuge bowl as recited in claim 4, wherein said bottom surface of said fin angles upwardly and outwardly at an angle of between about 3° and 7° relative to horizontal.

6. A centrifuge bowl as recited in claim 2, wherein said fin is of a length which is at least about 20 percent of said width of said cylindrical, annular collection region.

7. A centrifuge bowl as recited in claim 2, wherein said fin angles upwardly and outwardly at an angle of between about 3° and 7° and has a length of at least about 25 percent to 60 percent of the width of said cylindrical, annular collection region.

8. A centrifuge bowl as recited in claim 2, said bottom internal surface of said outer bowl being angled upwardly and outwardly, wherein said central portion of said passageway narrows as it radiates outward.

9. A centrifuge bowl as recited in claim 8, said fin being angled upwardly and outwardly at an angle at least equal to an inclination angle of said bottom internal surface of said outer bowl.

10. A centrifuge bowl assembly as recited in claim 9, said fin being angled upwardly and outwardly at an angle greater than an inclination angle of said bottom internal surface of said outer bowl.

11. A centrifuge bowl assembly as recited in claim 2, wherein a bottom surface of said fin angles upwardly and outwardly at an angle of between about 3 degrees and 7 degrees relative to horizontal wherein said internal spacer comprises a bottom member defining the entirety of said bottom external surface of said internal spacer, and wherein an annular recess is integrally formed in said bottom member immediately adjacent to and in concentric relation to the entirety of said fin.

12. A centrifuge bowl assembly for extracorporeal blood processing, including:

a rotatable cylindrical outer bowl having a bottom internal surface and an adjoining substantially vertical, internal sidewall;

a cylindrical internal spacer, interconnected within said outer bowl for driven rotation therewith having a bottom external surface and an adjoining a substantially vertical, external sidewall, said internal spacer comprising at least top and bottom members of molded plastic construction, wherein the bottom internal surface of said outer bowl and the bottom external surface of said internal spacer define an outwardly extending passageway, said passageway includes a central portion and an adjoining peripheral portion, said peripheral portion being disposed between the bottom internal surface of the outer bowl and an annular fin extending outwardly from said internal sidewall of said internal spacer, said passageway therebetween terminating in an annular, upward-facing port having a first width, and wherein said substantially vertical, internal sidewall of said outer bowl and the substantially vertical, external surface of said internal spacer define a substantially cylindrical, annular collection region therebetween, said cylindrical, annular collection region being in fluid communication with said annular, upward-facing port and having a second width greater than said first width of said port, said bottom member including said fin and having an annular recess in the bottom external surface immediately adjacent to said fin;

a stator assembly, interconnected to a top end of said outer bowl, for introducing blood and a wash solution into said passageway and to remove the wash solution and undesired blood components from said cylindrical, annular collection region during rotation of said outer bowl and internal spacer, wherein red blood cells accumulate in an outer, annular ring immediately adjacent to said vertical, internal sidewall, said outer ring of

accumulated red blood cells being packed substantially uniformly along the height thereof.

13. A centrifuge assembly for extracorporeal blood processing, including;

a rotatable cylindrical outer bowl;

a cylindrical internal spacer interconnected with said outer bowl for driven rotation therewith, wherein said outer bowl and internal spacer define a bottom, outwardly extending passageway therebetween terminating in an annular, upward-facing port having a first width, said passageway including a central portion and a peripheral portion disposed between the outer bowl and an annular fin extending from said internal spacer, and wherein said outer bowl has a substantially vertical internal sidewall and said internal spacer has a substantially vertical external surface to define a substantially cylindrical, annual collection region therebetween, said collection region being in fluid communication with said annular, upward-facing port and having a second width greater than said first width; and

a stator assembly for introducing blood and a wash solution into said bottom passageway and to remove the wash solution and undesired blood components in the introduced blood during rotation of said outer bowl and internal spacer, wherein red blood cells in the introduced blood accumulate in an outer, substantially cylindrical annual ring immediately adjacent to said substantially vertical, internal sidewall of the outer bowl, said outer ring of accumulated red blood cells having a substantially uniform thickness and being packed substantially uniformly along the height thereof, and said outer ring of accumulated red blood cells having a substantially uniform density gradient along the height of the outer ring, wherein said outer ring of red blood cells accumulates to a thickness sufficient to cover said port prior to introduction of wash solution, and wherein during introduction of wash solution at least a portion of said wash fluid solution flows through said port and said wash solution is directed by said fin into the bottom of said outer ring to wash said accumulated red blood cells, said wash solution and additional blood components accumulating in an inner layer of the annular collection region.

14. A centrifuge assembly as recited in claim 13, wherein said central portion of said bottom passageway becomes narrower as it extends outward, and wherein said peripheral portion of said bottom passageway is flared relative to an outer end of said central portion of said bottom passageway.

15. A centrifuge assembly as recited in claim 13, wherein said fin angles upwardly and outwardly at an angle of between about 3 degrees and 7 degrees and has a length of at least about 25% to 60% of the width of the cylindrical, annular collection region, wherein said wash solution is directed into said annular collection region at an acute angle transverse to said outer ring of accumulated red blood cells.

16. A centrifuge assembly as recited in claim 13, wherein after introduction of wash solution the outer ring of accumulated red blood cells is washed to form a washed red blood cell product having a hematocrit above about 42%.

17. A centrifuge assembly as recited in claim 13, wherein said blood and said wash solution are introduced into said bottom passageway at rates of at least about 300 ml./min. and at least about 500 ml./min., respectively.

18. A centrifuge assembly as recited in claim 13, wherein said introduced blood includes an anticoagulant, and where said washing provides for a mass anticoagulant removal of at least about 98%.

* * * * *

US005417650A

United States Patent [19]

Gordon

[11] Patent Number: 5,417,650

[45] Date of Patent: May 23, 1995

[54] **APPARATUS FOR SEPARATING PLASMA AND OTHER WASTES FROM BLOOD**

[75] Inventor: **Lucas S. Gordon**, The Woodlands, Tex.

[73] Assignee: **Advanced Haemotechnologies**, The Woodlands, Tex.

[21] Appl. No.: **154,238**

[22] Filed: **Nov. 18, 1993**

Related U.S. Application Data

[63] Continuation of Ser. No. 844,232, Mar. 2, 1992, Pat. No. 5,298,016.

[51] **Int. Cl.**[6] **A61M 1/00**

[52] **U.S. Cl.** **604/4**; 604/6; 210/321.63; 415/900

[58] **Field of Search** 604/4, 5, 6; 210/321.63, 321.75, 321.68, 321.67, 107, 216, 645, 780, 781, 782; 415/120, 900

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,179,384	4/1965	Anderson	415/120 X
3,567,030	3/1971	Loeffler et al.	210/321
3,864,055	2/1975	Kletschka et al.	415/900 X
4,082,668	4/1978	Zeineh et al.	210/129
4,216,770	8/1980	Cullis et al.	128/214
4,312,757	1/1982	Brumfield	210/321.63 X
4,594,152	6/1986	Gullichsen	209/273
4,631,050	12/1986	Reed et al.	604/4
4,664,682	5/1987	Monzen	55/178
4,675,106	6/1987	Schoendorfer et al.	210/232
4,737,139	4/1988	Zupkas et al.	604/4
4,776,964	10/1988	Schoendorfer et al.	210/782
4,790,942	12/1988	Scmidt et al.	210/650
4,834,890	5/1989	Brown et al.	604/6 X
4,871,462	10/1989	Fischell et al.	210/651
4,909,780	3/1990	Ouriel et al.	604/4
4,935,002	6/1990	Gordon	604/4
4,954,251	9/1990	Barnes et al.	210/806
4,968,600	11/1990	Haraguchi et al.	435/2
5,029,876	7/1991	Orlando et al.	277/56
5,096,127	3/1992	Young	241/46.17
5,158,533	10/1992	Strauss et al.	604/4
5,192,438	3/1993	Frejburg	210/413
5,263,924	11/1993	Mathewson	604/4

FOREIGN PATENT DOCUMENTS

0112152	6/1984	European Pat. Off.	3/1
0232885	8/1987	European Pat. Off.	405/604
850087	7/1981	U.S.S.R.	3/1

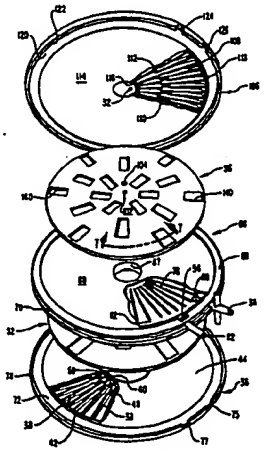
Primary Examiner—Sam Rimell

Attorney, Agent, or Firm—Workman, Nydegger & Seeley

[57] **ABSTRACT**

An apparatus is provided for separating cellular components of blood (red blood cells, white blood cells and platelets) from waste components (plasma, anticoagulant, toxins, and other relatively small molecules). The presently preferred embodiment is a two stage plasma separator apparatus. The first stage is comprised of a first chamber having inlet means for admitting blood requiring separation of cellular components from waste components, and outlet means for discharging blood processed in said first chamber. A first filter means is associated with the first chamber for separating cellular components from waste components of blood, the first filter means including first waste outlet means for discharging waste components of blood processed in the first chamber. First rotating means are associated with the first filter means for producing movement of cellular components of blood passing between the inlet means and the outlet means of the first chamber in order to substantially prevent obstruction of the first filter means by said cellular components of blood. The second stage is similar to the first, but has in addition to second filter means and second rotating means, wash inlet means for introducing wash solution to the blood processed in the first stage, so as to accomplish more thorough cleansing thereof. One feature of the present invention is the use of rotors as rotating means, and further providing the rotors with wedge shaped cavities to cause turbulence, and thereby further increase the filtration rate of waste components through the first and second filter means.

4 Claims, 6 Drawing Sheets



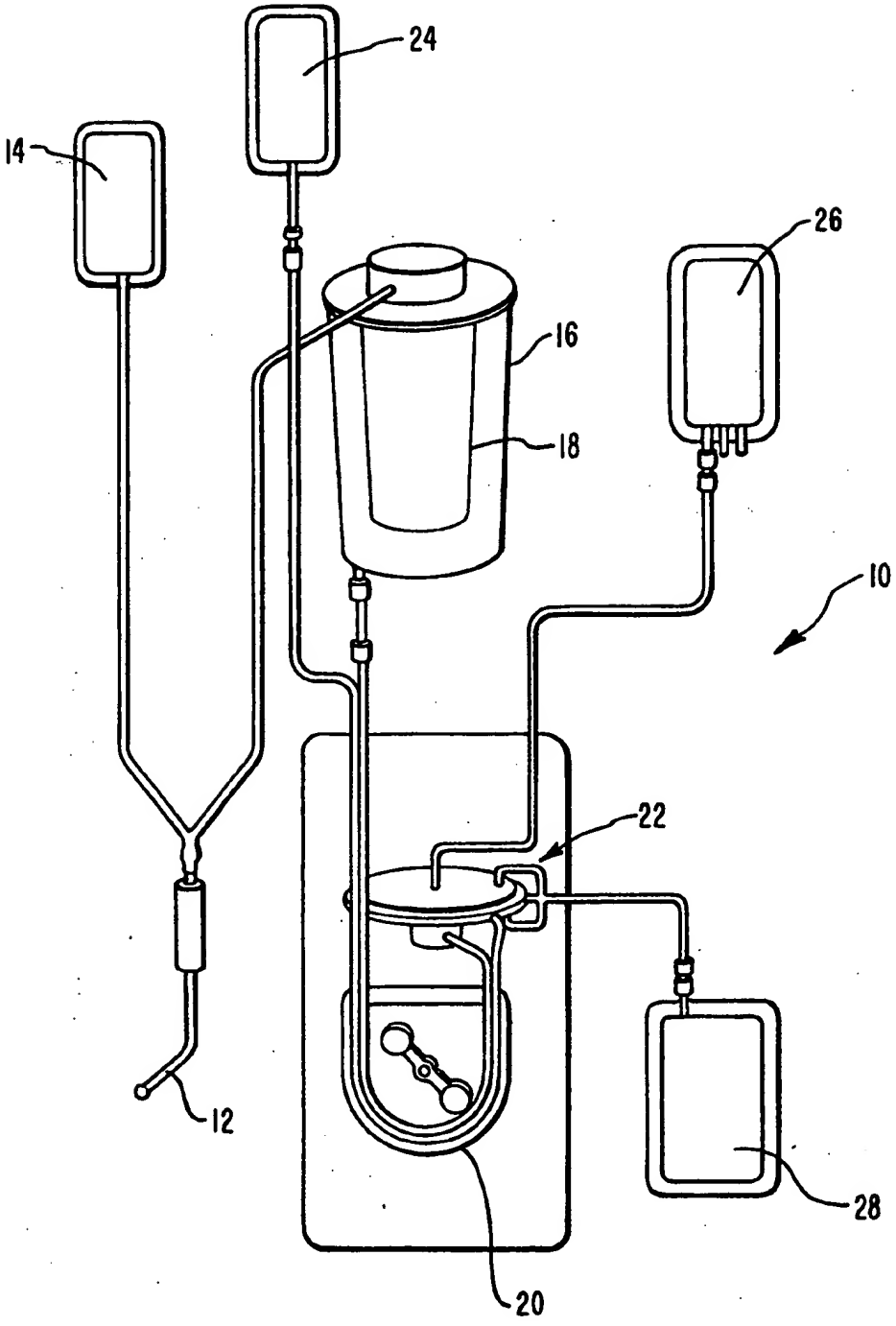


FIG. 1

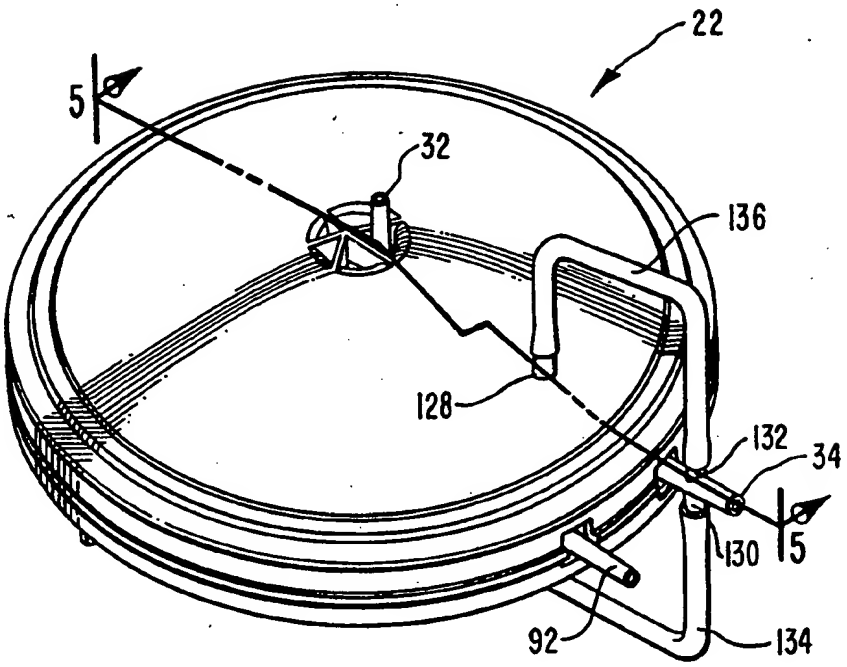

22
5
32
136
128
132
34
130
5
92
134

FIG. 2

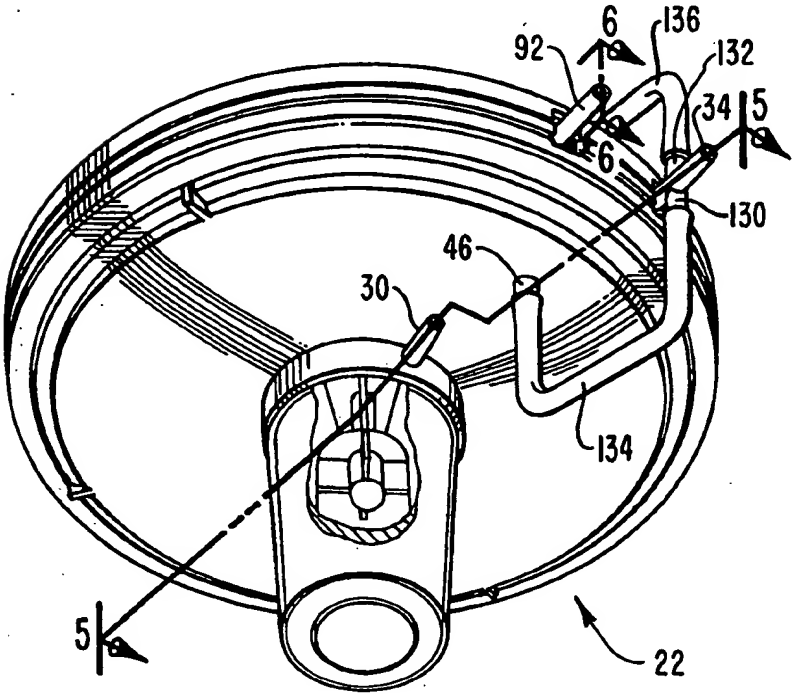

6
136
92
132
34
5
6
130
46
30
134
5
22

FIG. 3

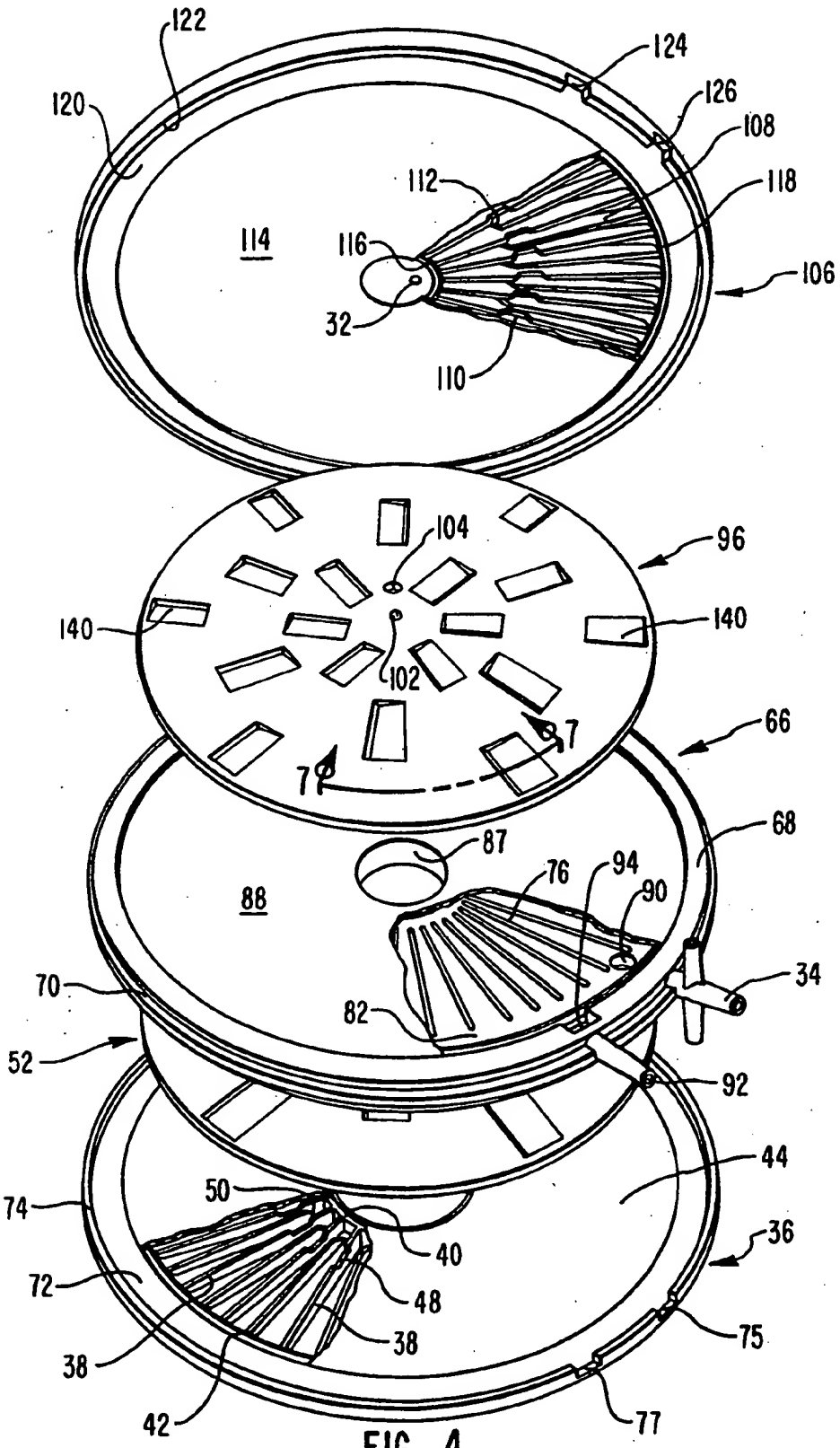

122
124
120
126
108
112
118
114
116
106
32
110
104
96
140
140
102
66
7
7
87
68
87
76
94
88
90
34
70
82
52
92
44
50
74
40
36
72
48
38
75
38
42
77

FIG. 4

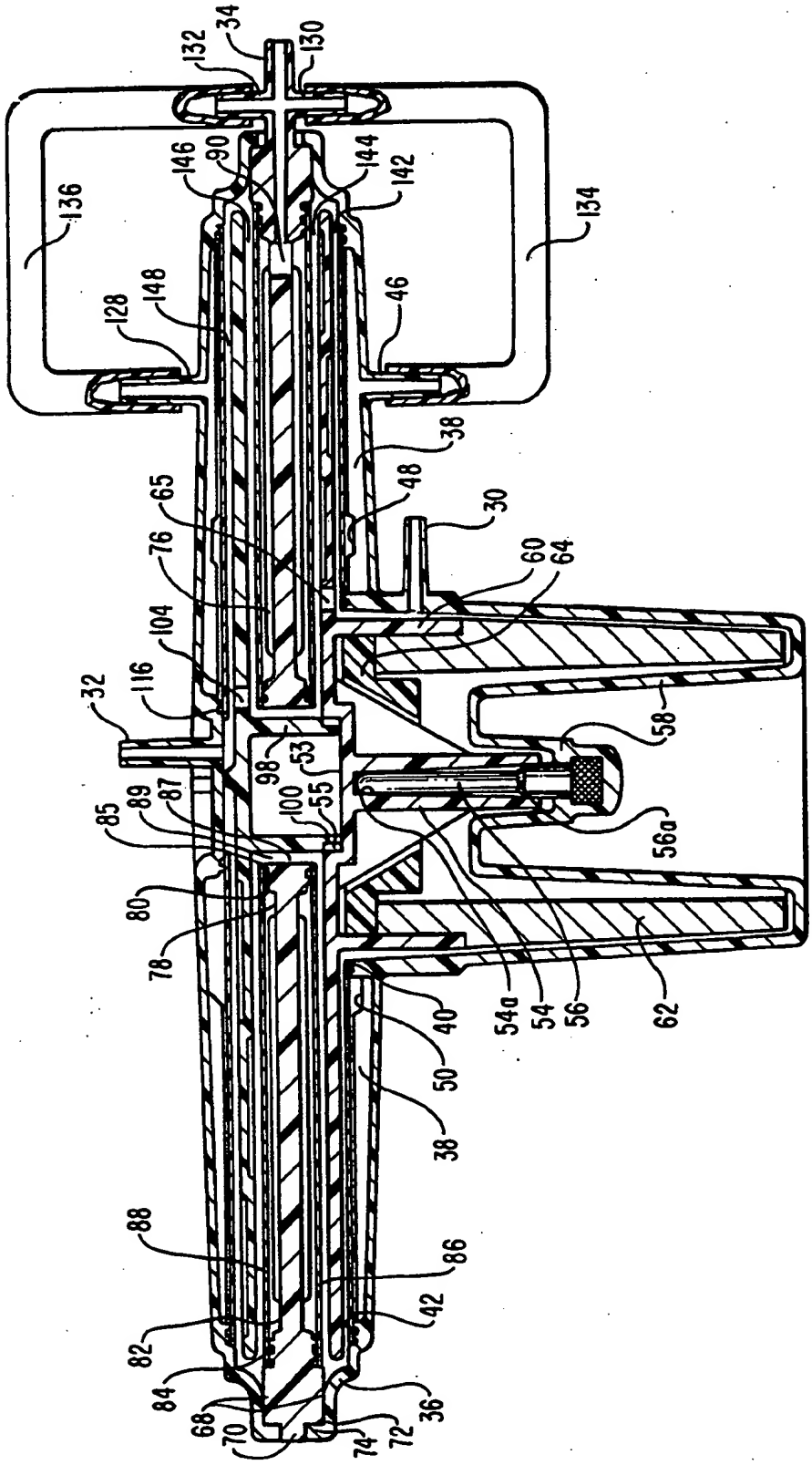


FIG. 5

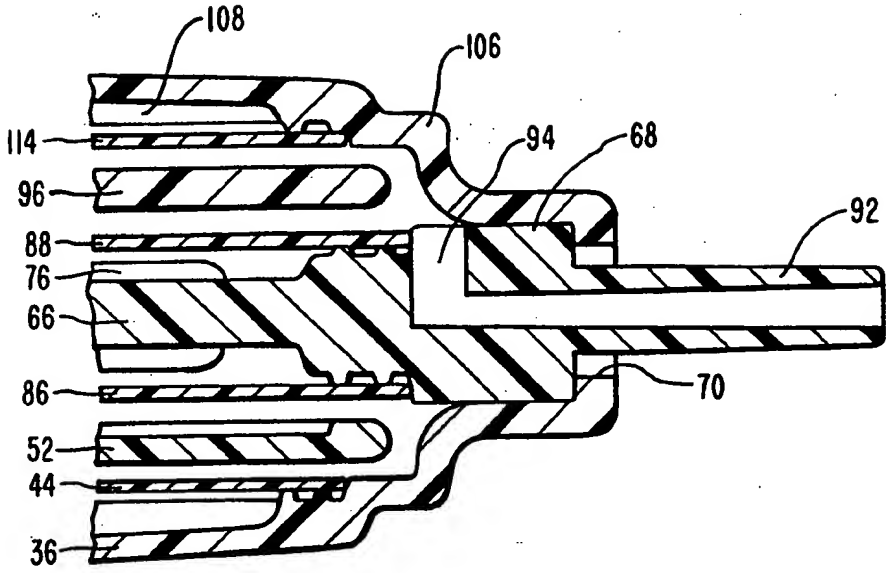


FIG. 6

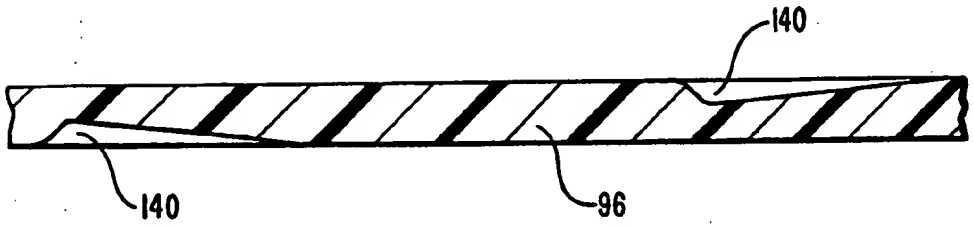


FIG. 7

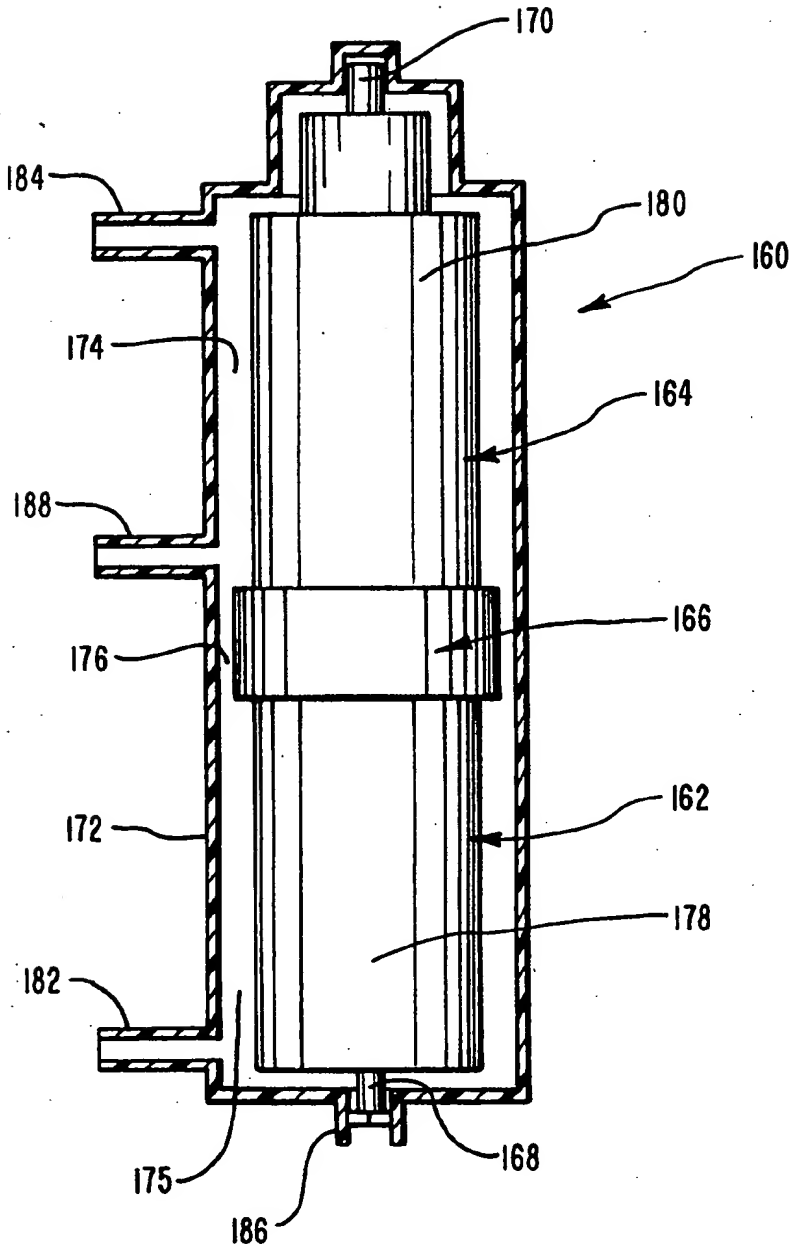


FIG. 8

APPARATUS FOR SEPARATING PLASMA AND OTHER WASTES FROM BLOOD

This application is a continuation of application Ser. No. 07/844,232, filed Mar. 2, 1992, now U.S. Pat. No. 5,298,016.

BACKGROUND OF THE INVENTION

1. Technical Field

The present invention relates to apparatus used in processing, cleansing and reconstituting blood for use by a patient, such as during surgical procedures, and more specifically to apparatus for filtering blood plasma and washing cellular components of blood to remove unwanted waste components.

2. Background Information

Most surgical procedures result in some loss of blood from associated surgical incisions. Injured patients can also often experience external and internal bleeding. If blood loss from injury or surgery is substantial, it becomes necessary to replenish lost blood through transfusion.

In many instances, it is possible to collect a patient's blood for use in replacing most or even all of the blood losses. It will be readily appreciated that blood collected from a wound or a surgical site will contain tissue fragments, lysed blood cells, and other unwanted substances. Such blood must be treated for removal of unwanted substances before it is safe for reinfusion into the patient.

The general procedure of collecting a patient's blood, cleansing it, and then returning it to the patient is sometimes referred to as autotransfusion. Where autotransfusion is possible, it is a strongly preferred way of replacing a patient's blood losses. One reason that autotransfusion is so preferred is that it avoids incompatibility problems which sometimes can occur when giving transfusions of blood obtained from someone other than the patient. Use of a patient's own blood to replace blood losses has also become increasingly important in view of issues relating to the safety of replacement blood, such as the prevalence of acquired immune deficiency syndrome (AIDS) or other diseases among blood donors in some locales. Because of these benefits, and others, autotransfusion is often the method of choice for minimizing loss of cellular blood components during diverse procedures ranging from surgery to plasma exchange therapy, and is likely to become increasingly important in the future.

The process of removing blood plasma and other unwanted substances without any cleansing of the blood is commonly referred to as plasmapheresis. Plasmapheresis has long been practiced through use of filters having a pore size large enough to pass plasma and other unwanted substances found in the blood, such as anticoagulant, toxins and components of lysed cells (which, for purposes of brevity and simplicity, shall sometimes hereinafter be referred to collectively as the "waste components" of blood), but small enough to retain intact cells, such as red blood cells, white blood cells and platelets (which shall sometimes hereinafter be referred to collectively as the "cellular components" of blood). Plasmapheresis has also been practiced through use of a centrifuge to separate plasma and other suspended waste components from the denser cellular components, and then removing the plasma and associated waste components.

Simple removal of plasma and associated waste components is not adequate to remove all waste materials associated with blood. It has been found that much more thorough cleansing of blood can occur if the cellular components are washed after the plasma is removed. U.S. Pat. No. 4,631,050 describes a process of autotransfusion utilizing a membrane for filtration to separate waste components from cellular components. That patent describes an initial filtration to remove gross debris, followed by addition of a washing solution to reconstitute the blood, and then subjecting the reconstituted mixture to another filtration step in order to remove remaining waste components. Although more effective at cleansing blood than simple plasmapheresis, there is a tendency for cellular components to clog the filter when utilizing this type of process. This is a serious problem because it seriously limits the flow rate of such a device, making it impractical for autotransfusion.

Numerous attempts were thereafter made to prevent buildup of cellular components on the filter membrane. One of the more effective solutions is set forth in U.S. Pat. No. 4,935,002, which was issued to the inventor of the present invention, and which is hereby incorporated by reference as though separately set forth herein. That patent describes a high speed filter for rapidly cleansing blood so that it can realistically be depended upon as a source of blood for autotransfusion. The plasma separator apparatus disclosed in U.S. Pat. No. 4,935,002 includes within a single housing a first filtration zone where waste components of blood are separated from the cellular components; a washing zone where a wash solution is mixed with the cellular components; and a second filtration zone where wash solution and residual waste components are separated from the cellular components. A rotating disk is used to create a shear force which prevents cellular components from building up and clogging the filter pores, and also serves to prevent clotting. Although a substantial improvement over previous apparatus for conducting plasmapheresis or for cleansing blood of unwanted waste materials, the apparatus disclosed in U.S. Pat. No. 4,935,002 could still be improved upon. For example, it was found that the apparatus of U.S. Pat. No. 4,935,002 was difficult to build within tolerances necessary to avoid unwanted mixing between the two filter zones at a reasonable cost. It was also discovered that the flow rate of blood through the device disclosed in that patent was slower than desirable and did not cleanse the cellular components of blood as effectively as desired.

SUMMARY OF THE INVENTION

It is a primary object of the present invention to provide improved apparatus for effecting the cleansing of blood to remove unwanted waste materials so that it is suitable for infusion into a patient.

Another object of the present invention is to provide apparatus for cleansing blood capable of more rapid flow rates than available in previous devices.

Yet another object of the present invention is to provide apparatus for cleansing blood which remove more of the waste components of blood than was removed by previous devices.

A still further object of the present invention is to provide an apparatus requiring less critical tolerances so that it can be produced more economically.

Additional objects and advantages of the invention are set forth hereinbelow in the detailed description, or will be appreciated by the practice of the invention.

To achieve the foregoing objects, and in accordance with the invention as embodied and broadly described herein, a plasma separator apparatus is provided which is capable of rapid, yet thorough cleansing of blood in order to remove unwanted substances.

More specifically, the present invention provides an apparatus for separating cellular components of blood (red blood cells, white blood cells and platelets) from waste components (plasma, anticoagulant, toxins, and other relatively small molecules).

The presently preferred embodiment is a two stage plasma separator apparatus. The first stage is comprised of a first chamber having inlet means for admitting blood requiring separation of cellular components from waste components, and outlet means for discharging blood processed in said first chamber. A first filter means and associated waste outlet means is associated with the first chamber for separating waste components from cellular components of blood. First rotating means are associated with the first filter means in order to produce movement of cellular components of blood as blood passes between the inlet means and the outlet means of the first chamber in order to substantially prevent obstruction of the first filter means by said cellular components of blood.

The second stage is similar to the first, but has in addition to second filter means and second rotating means, wash inlet means for introducing wash solution to the blood processed in the first stage, so as to accomplish more thorough cleansing thereof.

An important feature of the present invention is the use of rotors as rotating means, and providing the rotors with wedge shaped cavities to cause turbulence, which significantly increases the filtration rate of waste components through the first and second filter means.

BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings, which represent the best mode presently contemplated for carrying out the present invention:

FIG. 1 is a schematic representation of an autotransfusion system, one component of which is the plasma separator of the present invention;

FIG. 2 is a perspective view of the top of the presently preferred embodiment of the plasma separator of the present invention;

FIG. 3 is a perspective view of the bottom of the plasma separator of FIG. 2;

FIG. 4 is a partially exploded view of the plasma separator of FIG. 2, which serves to illustrate the principal components thereof;

FIG. 5 is a cross-sectional view taken along lines 5—5 of FIG. 2;

FIG. 6 is a cross-sectional view taken along lines 6—6 of FIG. 3;

FIG. 7 is a cross-sectional view taken along lines 7—7 of FIG. 4; and

FIG. 8 is a schematic representation of another embodiment of a plasma separator in accordance with the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention is directed to a plasma separator apparatus for cleansing blood so that it can be safely reinfused into a patient. Such apparatus will have wide applications, including removal of waste components from blood collected during surgery, including anticoagulant; plasma exchange therapy; removal of glycerin and other storage agents from blood frozen for storage; and any other application requiring separation of cellular components of blood from unwanted substances which are susceptible to separation through use of a filtration system. For purposes of brevity and simplicity, the discussion herein will be principally directed to the processing of blood during a surgical procedure for use in autotransfusion. It should be appreciated, however, that the teachings herein will be readily transferable to other applications involving separating cellular components of blood from plasma and other waste components.

Reference is first made to FIG. 1, which illustrates the use of a plasma separator apparatus in accordance with the present invention as a element of an autotransfusion system. Autotransfusion involves removal of blood from a patient, processing it for removal of unwanted components, and returning it to the patient. In order to be practical, the processing of a patient's blood must be accomplished quickly, yet thoroughly.

The autotransfusion system of FIG. 1, identified generally by reference numeral 10, satisfies these needs. Autotransfusion system 10 is configured for use in recovering blood from a surgical site so that it can be cleaned and returned to the patient. A sucker 12 is used to aspirate blood from a surgical site. A source of anticoagulant 14 is coupled to sucker 12 so that mixing of anticoagulant occurs quickly, thereby minimizing formation of blood clots. Aspirated blood and anticoagulant are drawn into a conventional blood collection reservoir 16, which includes a filter 18 having a pore size which will remove large particles such as blood clots, pieces of tissue, orthopedic cement, and the like, but which will pass cellular components of blood. Blood collection reservoir 16 also serves to effect defoaming of blood collected therein.

A roller pump 20 is advantageously used to pump blood from collection reservoir 16 into a plasma separator, a presently preferred embodiment of which is depicted generally by reference numeral 22. A wash solution, preferably saline, is also pumped into plasma separator 22 from a source 24. As described in detail below, the wash solution is mixed with partially cleansed blood in order to effect more thorough separation of waste components from the cellular components of the blood being processed by the plasma separator. Cleansed blood processed by plasma separator 22 is collected in a blood collection bag 26, and from there it is returned to the patient, typically by conventional gravity infusion. Plasma, anticoagulant, and other waste components of the blood are collected in a waste collection bag 28, which may be discarded.

STRUCTURE OF THE PREFERRED EMBODIMENT OF FIGS. 2-7

The presently preferred embodiment of the plasma separator of the present invention is illustrated in FIGS. 2 through 7. FIGS. 2 and 3 show top and bottom perspective views of plasma separator 22. Referring first to FIG. 3, it may be seen that the underside of plasma separator 22 has a blood inlet port 30 which functions as a means for admitting blood into the plasma separator which requires separation of cellular components from waste components of blood. It is advantageous to introduce blood at an underside location so that air can be most efficiently expelled from the plasma separator as it is brought into operation. As seen in FIG. 2, processed

blood suitable for autotransfusion is discharged from plasma separator 22 through blood outlet port 32. Waste components are removed from the plasma separator to a waste collection bag through waste outlet port 34.

Referring now to FIG. 4, plasma separator 22 is comprised of several component parts which interact to effect thorough cleansing of blood introduced through blood inlet port 30. Beginning at the bottom of FIG. 4 and working upwardly, the first of these components is a generally circular bottom plate 36. The upper face of bottom plate 36 is preferably slightly concave and provided with a series of radial raised ridges 38. The ridges utilized in the presently preferred embodiment of FIGS. 2–7 are configured so as to decrease in height when moving from the more central portion of bottom plate 36 toward the outside thereof along the concave surface of the bottom plate. This structure provides a generally level upper surface.

A filter 44 rests upon the generally level upper surface of ridges 38, and is secured to annular inner and outer rings 40 and 42 in conventional fashion so that nothing can leak past the edges of the filter. The diameter of bottom plate 36 at the location of the outermost edge of outer ring 42 is preferably about 6 inches, and the width of ring 42 is preferably about $\frac{1}{8}$ inch. Filter 44 is advantageously constructed from a biocompatible material having a pore size suitable for passing plasma and other waste components of blood but which will not pass the cellular components of blood. Filter 44 is also about 6 inches in diameter, so the outermost $\frac{1}{8}$ inch will be affixed to the outer ring 42. The center of filter 44 is cut out to conform to inner ring 40. Ridges 38 support filter 44 while defining channels through which waste fluid can flow as it passes through filter 44.

A waste outlet port 46 (see FIGS. 3 and 5) is provided on the underside of bottom plate 36 to serve as means for discharging waste components of blood which have passed through filter 44. Ridges 38 are preferably provided with notches 48 and 50 in order to permit unrestricted flow of waste components to and through waste outlet port 46.

The second component of plasma separator 22 is a rotor 52. Rotor 52 is circular in shape, and is about $5\frac{3}{4}$ inches in diameter, thereby leaving a gap of approximately $\frac{1}{8}$ inch between the circumferential surface of the rotor and the inner edge of rim 72 of bottom plate 36. As best seen in FIG. 5, the underside of rotor 52 is provided with a cylindrically shaped projection 54. Projection 54 is provided with a hollow bore 54*a* which is sized so as to receive a shaft 56 which is secured to and extends upwardly from chamber 58 of bottom plate 36. The lower end of projection 54 is designed to rest upon a beveled ledge 56*a* at the base of shaft 56, thereby supporting rotor 52 for rotation around shaft 56. Projection 54 of rotor 52 serves as a bearing which permits rotor 52 to rotate freely about shaft 56, yet also provides lateral support to insure that the rotor maintains its orientation with respect to filter 44. The lengths of projection 54 and shaft 56 are selected to as to leave a small gap between the underside of rotor 52 and the top of filter 44. For reasons explained below, it is presently preferred that this gap be about 0.026 inches.

The underside of rotor 52 is also provided with an annular flange 60. An annular magnet 62 and associated collar 64 are affixed to flange 60. This arrangement permits use of an external motor (not shown) having a rotating magnetic coupler capable of magnetically coupling with magnet 62. In use, application of a rotating magnetic force on magnet 62 results in rotation of rotor 52 without requiring the use of rotating seals, or the like. The upper side of rotor 52 has a cylindrical recess 53 (see FIG. 5), and a pair of projecting keys 55 for mechanical coupling to a second rotor, as explained below. Rotor 52 is provided with a small hole 65 (see FIG. 5) to facilitate debubbling as the plasma separator is brought into operation.

The next component of plasma separator illustrated in FIG. 4 is a center plate 66. Center plate 66 is circular in shape and of the same diameter as bottom plate 36. Both sides of center plate 66 are bounded by a circumferential rim 68 and flange 70. The bottom rim 68 and flange 70 are adapted to interface with a corresponding rim 72 and lip 74 provided on the upper surface of bottom plate 36. This arrangement permits bottom plate 36 to be secured to the underside of center plate 66 in a fluid-tight manner, thereby forming a first chamber.

Both sides of center plate 66 are provided with a plurality of radial ridges 76. In the preferred embodiment of FIGS. 2–7, ridges 76 increase in height as they extend radially outward. Ridges 76 are bounded at their inside end by a gap 78 and an inner annular ledge 80, and on the outside by another gap 82 and an annular ridged ledge 84. Filters 86 and 88 are secured to the lower and upper sets of ledges 80 and 84. Filters 86 and 88 are preferably made of the same material as filter 44, and are also about 6 inches in diameter. The center portion of filters 86 and 88 are removed so that they cover the area between ledges 80 and 84. As with ridges 38 on the bottom plate, ridges 76 of the center plate provide support for filters 86 and 88 while providing a channel for flow of fluid passing through the filters.

The center of center plate 66 is provided with an annular collar 85 forming a cylindrical hole 87 through center plate 66. The diameter of hole 87 is slightly larger than the cylindrical recess 53 of the bottom plate 36, preferably about 0.022 inches, for reasons set forth below. When the bottom plate, rotor 52 and center plate 66 are assembled, there is preferably a gap of about 0.026 inches between rotor 52 and filters 44 and 86.

Center plate 66 is provided with a waste outlet port 34, which serves as means for discharging waste components of blood which have passed through both filters 86 and 88 to a waste collection bag. Waste outlet port 34 is in fluid communication with a hole 90 passing through gap 82. This hole permits waste components passing through filters 86 and 88 to join together and pass out through waste outlet port 34.

Center plate 66 is also provided with a wash inlet port 92 which is adapted for attachment to a source of wash solution. As best seen in FIG. 6, wash inlet port 92 advantageously opens through an aperture 94 located on the upper side of rim 68. Bottom plate 36 is provided with two cutouts 75 and 77 in lip 74 to accommodate ports 34 and 92 (see FIG. 4).

The next component of plasma separator 22 shown in FIG. 4 is a second rotor 96. Rotor 96 is of the same general size and shape as rotor 52, except, as best seen by reference to FIG. 5, it has projecting from the bottom thereof a cylindrical extension 98 which is sized to pass through hole 87 and to be received by cylindrical recess 53 of lower rotor 52. A pair of keyways 100 mate with keys 55 of lower rotor 52 so that the two rotors are mechanically coupled together. Hence, rotation of the lower rotor 52 will cause upper rotor 96 to rotate as well. As noted above, there is an annular gap 89 of

approximately 0.022 inches between the edge of center plate **66** in the region of hole **87** and cylindrical extension **98**. This gap provides a flow path for cellular components of blood as they move through plasma filter **22**, thereby serving as an outlet means from the first chamber and also as inlet means into a second chamber in which rotor **96** sits.

The center of the upper side of rotor **96** has a small projecting nub **102**, which serves as a thrust bearing to keep rotor **96** from rising during use, and thus maintaining the appropriate gap between rotor **96** and filter **114**, described below. A small hole **104** passes through rotor **96** to help in debubbling plasma separator **22** as it is initially primed and brought into operation, similar to hole **65** found in rotor **52**.

The final component illustrated in FIG. **4** is top plate **106**. Top plate **106** is similar in construction to bottom plate **36**. It is provided with ridges **108** similar to ridges **38**, including notches **110** and **112** which correspond to notches **48** and **50**. A filter **114** is affixed to an inner annular ring **116** and an outer annular ring **118**, the centermost portion of filter **114** being removed to expose blood outlet port **32**. Once again, the various components are constructed so as to leave a gap of approximately 0.026 inches between the top of rotor **96** and filter **114**. Like bottom plate **36**, top plate **106** has a rim **120** and a lip **122** adapted to interface with rim **68** and flange **70** of the center plate **66**, thereby forming a second chamber. It is also provided with cutouts **124** and **126** in lip **122** to accommodate ports **34** and **92**. A waste outlet port **128** (FIG. **5**) is provided on the upper side of top plate **106** to serve as means for discharging waste components of blood which have passed through filter **114**. Advantageously so as to reduce the number of tubes which lead from plasma separator **22** to the waste collection bag, outlet port **34** is provided with a pair of extension ports **130** and **132**. Waste outlet ports **46** and **128** are connected to port **34** using tubing **134** and **136**. This arrangement results in all of the waste components being discharged from plasma separator **22** through a single outlet port.

It will be appreciated that filters **44** and **86** both pass plasma and other waste components from within the first chamber formed between bottom plate **36** and center plate **66**. The combination of these two filters in the presently preferred embodiment of the plasma separator as illustrated in FIGS. **2–7** serve as a first filter means for separating cellular components from waste components of blood. Waste outlet ports **34** and **46** serve as first waste outlet means for discharging waste components of blood processed within the first chamber. Similarly, filters **88** and **114** serve as second filter means situated within the second chamber formed by center plate **66** and top plate **106** for separating cellular components of blood from waste components. Waste outlet ports **34** and **128** serve as second waste outlet means for discharging waste components of blood processed in the second chamber.

An important feature of the presently preferred embodiment of the present invention involves an enhancement to the design of rotors **52** and **96**. As best seen by reference to FIG. **7**, both sides of the rotor **96** (and also rotor **52**) are provided with a plurality of wedge shaped cavities **140** to generate turbulence in blood being processed through the plasma separator, thereby substantially preventing the associated filter membranes from becoming clogged by cellular components of blood, as discussed more completely below in connection with a description of the operation of plasma separator **22**.

OPERATION OF THE PREFERRED EMBODIMENT ILLUSTRATED IN FIGS. 2–7

The operation of plasma separator **22** will now be described, following the pathway that blood will follow as it passes through the presently preferred embodiment of plasma separator in accordance with the present invention.

As noted above with respect to the autotransfusion system **10** of FIG. **1**, blood is admitted into plasma separator **22** through inlet port **30**, and then flows around the outside of magnet **62** and fills chamber **58**. At first, plasma separator **22** will be full of air which must be removed by "priming" the separator. During this priming stage, air flows upwardly around the periphery of rotors **52** and **96**, through holes **65** and **104** in the rotors, and through gap **89** near the center of center plate **66**, and then out of plasma filter **22** through blood outlet port **32**. Air also passes through the filters **44**, **86**, **88** and **114**, and out through waste outlet ports **46**, **128** and **34**.

As blood moves upwardly through plasma separator **22**, it first enters gap **142** (see FIG. **5**) located between lower rotor **52** and filter **44**. Plasma and other waste components of blood pass through filter **44**, and are discharged through waste outlet port **46**. In the absence of a spinning rotor, cellular components of blood would tend to accumulate and clog the pores of filter **44**, thereby significantly impairing its throughput volume of plasma and other waste components. Accordingly, plasma separator **22** is magnetically coupled to an external drive (not shown), which causes rotor **52** to rotate in a clockwise direction (looking upwardly from the bottom of bottom plate **36**). The rotation of rotor **52** imparts a shear force upon the cellular components of blood contained within gap **142**, thereby tending to keep them in movement rather than clogging the pores of filter **44**. Hence, rotor **52** functions as a first rotating means associated with the first filter means for producing movement of cellular components of blood passing between the inlet means and the outlet means of the first chamber in order to substantially prevent obstruction of the first filter means by those cellular components. The spinning rotor also prevents formation of blood clots as anticoagulant is removed.

In addition, as the rotor turns, blood follows the contour of wedge shaped cavities **140** from the shallow end to the abrupt rear face, at which point the blood is ejected in a manner which generates significant turbulence. The use of a plurality of wedge shaped cavities ensures numerous paths of turbulence as the rotor turns. This turbulence adds to the motion of cellular components caused by the shear forces, and significantly increases movement of cellular components within gap **142**, which in turn increases the throughput volume of waste components through filter **44** over a given period of time. Indeed, the configuration of wedge shaped cavities **140** illustrated in FIGS. **2–7** has been found to increase the filtration flow rate by approximately 15 percent over the flow rate of a rotor lacking such cavities.

It should be understood that although wedge shaped cavities are the presently preferred structure for imparting turbulence to blood flowing through plasma separator **22**, other structures could also be used to perform that function. For example, cavities of other shapes and

sizes would also be useful. Alternatively, it would be possible to provide a plurality of short posts projecting from the surface of the rotor. Even a plurality of simple spokes projecting from an annular hub in place of a rotor has been found capable of providing adequate swirling motion to give excellent results. One of ordinary skill in the art will appreciate that any structure which will generate some reasonable degree of turbulence could be used in place of the rotor illustrated in FIGS. 2–7 without departing from the teachings and concepts of the present invention; any rotating means for generating movement of the cellular components of blood will assist in keeping the pores of the filters clear and assist in moving the cellular components through the plasma separator.

The speed at which rotor **52** is turned has a direct effect upon the amount of clogging that will occur; turning the rotor at a faster rate increases the magnitude of shear forces applied to the cellular components and hence decreases the tendency for cellular components to clog the pores of the filters. The result is an increased filtration flow rate of waste components. Yet, there are practical limits to the speed of the rotor, because increasing the rate of rotation eventually leads to shear forces which damage the cellular components. The configuration of plasma separator **22**, utilizing wedge shaped cavities on the rotors permits the use of a relatively moderate rotor speed of about 750 rpm while maintaining excellent throughput volumes of waste components.

The flow of blood next moves upwardly past the outside edge of rotor **52** and then inwardly within gap **144** located between the top of rotor **52** and filter **86**. Additional waste components flow through filter **86**, while the cellular components continue to be stirred by the shear forces and turbulence generated by rotor **52**. Waste components passing through filter **86** are discharged from plasma separator **22** through waste outlet port **34**.

By the time the blood has traveled through gaps **142** and **144**, which shall sometimes hereinafter be referred to as the "first stage" of plasma separator **22**, a substantial amount of plasma and other waste components of the blood will be removed through filters **44** and **86**. A reduction of the hematocrit of the blood to about **50** as the blood completes its passage through the first stage has been found a desirable target which leaves the cellular components suspended in a sufficient volume of plasma to remain fluid, yet which removes much of the unwanted waste components contained in the blood entering blood inlet port **30**.

The blood next enters a "second stage" through gap **89** defined by the edge of annular collar **85** of center plate **66** and the surface of cylindrical extension **98** of top rotor **96**. In similar manner to the first stage, blood passes through gap **89** and then enters gap **146** located between filter **88** and the underside of rotor **96**. In similar manner to that discussed above with respect to the first stage of plasma separator **22**, rotor **96** functions as a second rotating means associated with second filter means (filters **88** and **114**) to prevent significant clogging of the pores of the filter means by cellular components of blood. The blood then moves generally outwardly toward the periphery of the rotor. Simultaneously, a wash solution, generally saline, is introduced through wash solution inlet port **92**, which functions as means for admitting wash solution into the second chamber for mixing with blood in the second chamber. The shear forces and turbulence caused by rotation of rotor **96** effect rapid mixing of the wash solution with the partially cleansed blood contained within gap **146**. Concurrently with the introduction of wash solution, waste components, now including wash solution as well as remaining plasma and other unwanted substances, flow through filter **88** and are discharged through waste outlet port **34**.

Again following the pattern of the first stage, the mixture of blood and wash solution flows upwardly around the edge of rotor **96** and into gap **148** formed between the top of rotor **96** and filter **114**. Additional mixing occurs between this mixture and wash solution which is continuously introduced through wash inlet port **92**. Waste components flow through filter **114**, for discharge through waste outlet port **128**. The high efficiency of mixing of wash solution with blood in the second stage results in very thorough cleansing of the cellular components of blood, even with relatively small volumes of wash solution. Indeed, the use of two stages and rotors having wedge shaped cavities **140** is so much more efficient than the device disclosed in U.S. Pat. No. 4,935,002, that it is possible to make plasma separator **22** smaller than the device disclosed in that patent. Cleansed blood, again at a hematocrit of about 50, finally exits plasma separator **22** through blood outlet port **32**.

It is important to the operation of plasma separator **22** that mixing not occur between the two stages. If mixing occurs, plasma separator **22** will operate as a single stage filter, and a loss of wash efficiency has been found to result. The primary cause presently known which results in unwanted mixing is the formation of Taylor vortices in the area of gap **89**.

A "Taylor Number" has been defined as the Reynolds Number for a system multiplied by the square root of the ratio of the annular gap **89**, divided by the radius at the gap. This reduces to the following formula:

$$T=N(G)^{1.5}(R)^{0.5}/V$$

Where:

T=Taylor Number
G=Width of Annular Gap **89**
R=Radius at Gap **89**
N=Rotor Speed
V=Viscosity

At a Taylor number of approximately 41 or greater, Taylor vortices will exist. The application of this formula was verified empirically by use of dye studies. Saline wash solution colored by use of a dye was observed as exiting only through the second stage waste outlets at Taylor Numbers below 41, but was observed to exit from the waste outlets of both stages at Taylor numbers greater than 41. In other experiments, it was discovered that a gap between the rotor and the outside casing of the device of U.S. Pat. No. 4,935,002 had to be about 0.008 inches to avoid Taylor vortices between the two "zones" of that device, a tolerance which was very difficult and expensive to obtain. In the present device, gap **89** can be increased to 0.022 inches, a measurement which is readily attainable at reasonable cost in a production device.

Plasma separator **22** is capable of processing blood at an input flow rate of up to about 400 milliliters per minute (ml/min), although it is contemplated that the normal flow rate will be about 100 ml/min. At this flow rate, approximately 100 ml/min of waste components will be removed from the first chamber. About 100

ml/min of wash solution is introduced into the second chamber, while about 100 ml/min of additional waste components are removed from the second chamber. When operating under these parameters, about 100 ml of processed blood will be collected in blood collection bag **26** each minute.

Although the two stage construction of plasma separator **22** is presently preferred, it would be a relatively single matter to add additional stages, should such be desirable for particular applications. It is to be understood that the use of additional stages is contemplated within the scope of the present invention.

STRUCTURE AND OPERATION OF THE ALTERNATIVE EMBODIMENT OF FIG. 8

FIG. **8** sets forth in schematic form an alternative embodiment of a plasma separator **160** constructed in accordance with the present invention. The device of FIG. **8** utilizes a pair of cylinders **162** and **164**, mechanically joined by an annular collar **166** so that both will rotate together. Cylinders **162** and **164** are advantageously disposed for rotation about pivot pins **168** and **170**. Suitable drive means (not shown), such as the use of a magnetic coupling system as shown above in connection with the presently preferred embodiment of FIGS. **2–7**, are provided to cause rotation of cylinders **162** and **164**.

Cylinders **162** and **164** are disposed within a cylindrical housing **172**, so that gaps **175** and **174** exist between cylinders **162** and **164**, respectively and the wall of housing **172**. Gap **176** exists between collar **166** and housing **172**.

First and second filters **178** and **180** are disposed over the surface of cylinders **162** and **164**, respectively, and the cylinders are advantageously provided with a plurality of orifices (not shown) to carry fluid from the outside of the cylinders, to the inside thereof.

In use, cylinders **162** and **164** are brought to a suitable operating speed, and blood is introduced through blood inlet port **182**. Blood flows upwardly within gap **175**, forcing air out through blood outlet port **184**. Plasma and other waste components pass through filter **178** within the first stage of plasma separator **160**, and then are discharged through waste outlet port **186**. The spinning of cylinder **162** generates shear forces at the surface of filter **178**, thereby preventing clogging of the pores of the filter.

As blood continues to rise within plasma separator **160**, it passes through gap **176** into the second stage of the plasma separator. Wash solution is introduced through wash inlet port **188** and is mixed with blood through operation of the rotating cylinder **164**. As in the first stage, waste components pass through filter **180** and are discharged through waste outlet port **186**. Cleansed blood is discharged from plasma separator **160** through blood outlet port **184**.

Although not illustrated, it will be readily appreciated that structures (such as wedge shaped cavities or protrusions) could be provided on the interior of housing **172** to generate additional turbulence, should that be desired to prevent filters **178** and **180** from becoming clogged during use. Inasmuch as the filters are themselves in motion in the embodiment of FIG. **8**, however, it is contemplated that adequate filtration rates will normally be obtained even without such additional structures.

The plasma separator apparatus and associated improvements to rotor design are significant improvements over previous apparatus for effecting the cleansing of blood to remove unwanted waste materials, thereby making it suitable for reinfusion into a patient. It is capable of more rapid flow rates than previous devices, which in turn permits it to be made smaller and less expensively without sacrificing effectiveness. Its construction is also such that manufacturing tolerances are less critical than previous designs, making it more economical to produce for commercial uses.

It will be appreciated that the present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive, and the scope of the invention is indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed and desired to be secured by United States Patent is:

1. A rotor for use in the separation of plasma and waste components of blood contained in said plasma from cellular components of blood comprising:

at least one surface to be placed in contact with blood from which plasma and waste components contained therein are to be separated from cellular components, said at least one surface being capable of generating shear forces upon the blood when the rotor is rotated;

said at least one surface being substantially planar and provided with a plurality of wedge shaped cavities for generating turbulence within said blood when the rotor is rotated.

2. A rotor as defined in claim **1**, wherein said at least one surface to be placed in contact with blood comprises two surfaces.

3. A rotor for use in the separation of plasma and waste components of blood contained in said plasma from cellular components of blood comprising:

two opposing surfaces to be placed in contact with blood from which plasma and waste components contained therein are to be separated from cellular components, each of said surfaces being capable of generating shear forces upon the blood when the rotor is rotated;

each of said surfaces being provided with a plurality of wedge shaped cavities for generating turbulence within said blood when the rotor is rotated.

4. A rotor as defined in claim **3**, further comprising means for connecting said rotor with a second rotor so that both rotate together.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,417,650
DATED : May 23, 1995
INVENTOR(S) : LUCAS S. GORDON

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

Title page, item [56], column 2, after listing of "Foreign Patent Documents," the following should be inserted:

--OTHER PUBLICATIONS

Factors Governing Mass Transport in Filters for Membrane Plasmapheresis, Michael J. Lysaght and Matthias Schmidt, Raven Press, New York (pub. 1983), pp. 113-127.

(Brochure) "The HaemoLite 2 now make autotransfusion totally automatic", Haemonetics Corporation (believe to have been published at least as early as 1991).

(Brochure) "The Evidence Shows . . .," Haemonetics Corporation--

Column 11, line 9, "single" should be --simple--

Signed and Sealed this

Twenty-fourth Day of October, 1995

Attest:

Attesting Officer

BRUCE LEHMAN

Commissioner of Patents and Trademarks